UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZANTAC (RANITIDINE)
PRODUCTS LIABILITY
LITIGATION
_____/

Golbenaz Bahtiar, *et al.,* on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

CASE NO:
JURY TRIAL DEMANDED

GlaxoSmithKline LLC, *et al.,*

Defendants.

MASTER MEDICAL MONITORING CLASS ACTION COMPLAINT AGAINST GSK DEFENDANTS[1]

[1] This Complaint is filed pursuant to Section II E of Pretrial Order 62 [DE 3083] entered in *In Re: Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924 (S.D. Fla. Case No. 9:20-md-02924-RLR).

Plaintiffs file this Master Medical Monitoring Class Action Complaint ("MMMC") on behalf of themselves and all others similarly situated against Defendants GlaxoSmithKline LLC, GlaxoSmithKline (America) Inc., and GlaxoSmithKline plc (collectively, "GSK"), and seek damages and equitable relief to remedy the harms caused by GSK's unlawful design, testing, manufacture, marketing, packaging, labeling, handling, distribution, storage, and/or sale of over-the-counter ("OTC") and prescription ranitidine-containing medications sold under the brand name Zantac.[2] Plaintiffs' allegations are based upon personal knowledge as to Plaintiffs' own conduct, investigation of counsel based on publicly available information, and the discovery conducted to date.

I. INTRODUCTION

Zantac is the branded name for ranitidine, a drug that was touted and sold for nearly four decades as a safe and effective heartburn and indigestion drug. Zantac and other Ranitidine-Containing Products were among the most popular heartburn drugs, used by thousands of people every day. Indeed, Zantac was the first-ever "blockbuster" drug to reach $1 billion in sales.

But recent scientific studies confirmed what GSK knew or should have known decades ago: ranitidine transforms over time and under natural conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is potent and dangerous. The U.S. Food and Drug Administration ("FDA") recognizes NDMA as "a probable human carcinogen"[3] and the

[2] All prescription and OTC ranitidine-containing medications, whether brand name, store brand, or generic, are referred to collectively as "Ranitidine-Containing Products." Brand name Ranitidine-Containing Products are referred to as Zantac.

[3] https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market.

World Health Organization has described it as "clearly carcinogenic."[4] Its only use is to induce cancerous tumors in animals as part of laboratory research and experiments; it has no medicinal purpose.

In 2019, an analytical pharmacy ran tests on Zantac and discovered the link between ranitidine and NDMA and that ranitidine itself is unstable and can break down into NDMA, particularly in the environment of the stomach. On September 13, 2019, the analytical pharmacy filed a citizen petition asking the FDA to recall all products that contain ranitidine. In early October 2019, the FDA ordered testing on Zantac and other Ranitidine-Containing Products and specified the protocols for such testing. Within days of the FDA's announcement, certain manufacturers recalled Zantac and Ranitidine-Containing Products in the United States and internationally. On November 1, 2019, the FDA announced that its recent testing showed "unacceptable levels" of NDMA in Zantac and other Ranitidine-Containing Products and requested that all manufacturers recall Zantac and other Ranitidine-Containing Products. Ultimately, on April 1, 2020, the FDA called for a withdrawal of Zantac and all other Ranitidine-Containing Products in the United States, citing unacceptable levels of NDMA in those drugs.

While any exposure to NDMA can be harmful, the FDA has set an allowable daily limit ("ADI") of 96 nanograms (ng) of NDMA. Tests conducted by the FDA and on behalf of the manufacturers themselves indicate that ranitidine contains NDMA in levels far in excess of the FDA's ADI even prior to ingestion. Thus individuals (including Plaintiffs) who ingested Zantac and other Ranitidine-Containing Products for years have been exposed to unsafe levels of carcinogenic NDMA. And that exposure has significantly increased their (and Plaintiffs') risk of

[4] R.G. Liteplo et al., Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine, World Health Organization (2002), https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

cancer—sometimes by more than 200%. As a result, Plaintiffs and the Classes need medical monitoring that is different than routine medical treatment to permit early detection of the Subject Cancers,[5] as well as treatments and/or medications.

Medical monitoring is a recognized cause of action or form of relief (depending on state law) that allows a plaintiff and class members to obtain diagnostic medical examinations that are funded and/or reimbursed by a defendant, when the defendant's tortious conduct has exposed the plaintiff and class members to an increased risk of harm that proximately causes the need for the comprehensive diagnostic examinations.

In other words, medical monitoring recognizes that plaintiffs and class members can be significantly harmed, notwithstanding the latent exposure of that harm. To obtain relief, plaintiffs generally must prove exposure to a hazardous substance at greater than background levels, caused by the defendant's tortious conduct, which significantly increases the risk of contracting a serious latent disease.[6] Typically, the proposed monitoring procedure must permit early detection, be reasonably necessary, and differ from routine medical treatment.[7]

Some states do not require a present physical injury as a condition to obtaining medical monitoring relief; rather, the injury is the exposure to the toxic materials and concomitant increased risk of harm, and/or the expensive diagnostic examinations plaintiff will incur as a result of that increased risk. Other states require a plaintiff to plead a physical manifestation (or present physical injury) of some sort, along with a significantly increased risk of harm.

---

[5] These cancers include serious and potentially fatal bladder, colorectal/intestinal, esophageal, gastric, liver, lung, pancreatic, and prostate cancers (the "Subject Cancers").
[6] *See, e.g.*, *Petito v. A.H. Robins Co., Inc.,* 750 So. 2d 103, 106-07 (Fla. Dist. Ct. App. 1999).
[7] *See, e.g., id*.

Plaintiffs and the Classes seek medical monitoring in those states where present physical injury is *not* required, and where a significantly increased risk of harm (and/or related diagnostic examination costs) is a legally sufficient injury.

Here, GSK *inter alia* designed, manufactured, distributed, packaged, labeled, marketed, and/or sold Zantac without proper expiration dates and appropriate packaging; failed to ensure the proper conditions for the manufacture, transportation, handling, and storage of Zantac; and failed to disclose material facts regarding the safety of Zantac and the dangers and risks associated with its intended use. In doing so, GSK breached its respective duties to Plaintiffs and the Classes.

This MMMC is drafted and organized based on the MDL Court's previous Orders.[8] As detailed below, Plaintiffs, individually and on behalf of the Classes (comprised of individuals who ingested GSK's Zantac in specific identified States), seek medical monitoring as a result of their exposure to GSK's prescription and/or OTC Zantac under the law of the State(s) in which each Plaintiff resided at the time of use.

II. JURISDICTION AND VENUE

1. This Court has original subject-matter jurisdiction over this action under 28 U.S.C. §1331 (federal question) and 18 U.S.C. §1964 (civil remedies). This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005, 28 U.S.C. §1332(d)(2), because: (a) there are at least 100 class members; (b) the matter in controversy exceeds $5 million, exclusive of interest and costs; and (c) at least one Plaintiff is a citizen of a different state than at least one Defendant. In addition, this Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. §1367.

[8] *See* Order Requiring Amended Master Pleadings [DE 3751] and Pretrial Order 62 [DE 3083] entered in *In Re: Zantac (Ranitidine) Products Liability Litigation*, MDL No. 2924 (S.D. Fla. Case No. 9:20-md-02924-RLR).

2. This Court has personal jurisdiction over GSK because GSK is a citizen of, and has its principal place of business in, Pennsylvania, as well as under 18 U.S.C. §1965(b) and (d) because GSK transacts business in Pennsylvania. This Court also has pendent personal jurisdiction over GSK.

3. In addition and/or in the alternative, GSK and/or its agents or alter egos each have significant contacts with each of the States and territories of the United States because they designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products within each of the States and territories of the United States, and/or they derived revenue from the sale of their Ranitidine-Containing Products in each of the States and territories of the United States, through the purposeful direction of their activities to the States and territories of the United States and purposeful availment of the protections of the laws of the States and territories of the United States, such that personal jurisdiction would be proper in those States and territories under traditional notions of fair play and substantial justice.

4. Venue is proper in this District under 28 U.S.C. §1391(b) because GSK is located in this District and a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District. GSK designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, and otherwise conducted extensive business, within this District.

III. PARTIES

A. The GSK Defendants

5. GSK designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold prescription and/or OTC Zantac.

6. Defendant GlaxoSmithKline LLC is a Delaware limited liability company with its principal place of business located at Five Crescent Drive, Philadelphia, Pennsylvania 19112.

Defendant GlaxoSmithKline LLC's sole member is Defendant GlaxoSmithKline (America) Inc., a Delaware corporation with its principal place of business in that state. Defendant GlaxoSmithKline LLC is a citizen of Delaware and Pennsylvania.

7. Defendant GlaxoSmithKline (America) Inc. is a Delaware corporation with its principal place of business located at 1105 North Market Street, Suite 622, Wilmington, Delaware 19801. Defendant GlaxoSmithKline (America) Inc. is a citizen of Delaware and Pennsylvania.

8. Defendant GlaxoSmithKline plc is a public limited company formed and existing under the laws of the United Kingdom, having a principal place of business at 980 Great West Road, Brentford Middlesex XO, TW8 9GS, United Kingdom. Defendant GlaxoSmithKline plc is a citizen of the United Kingdom.

9. Defendants GlaxoSmithKline LLC and GlaxoSmithKline (America) Inc. are direct or indirect subsidiaries or affiliates of Defendant GlaxoSmithKline plc. Collectively, these entities shall be referred to as "GSK." Defendant GSK was a manufacturer, distributor, and seller of brand prescription and OTC Zantac.

B. Non-Party Brand Manufacturers

Pfizer

10. Non-Party Pfizer Inc. ("Pfizer") is a U.S.-based corporation and was a manufacturer, distributor, and seller of brand OTC Zantac.

Boehringer Ingelheim (BI)

11. Non-Parties Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, and Boehringer Ingelheim USA Corporation, are U.S.-based corporations that are direct or indirect subsidiaries or affiliates of Non-Party Boehringer Ingelheim International GmbH, a German limited liability company. Non-Party Boehringer Ingelheim Promeco, S.A. de C.V. is a Mexican corporation that is a direct or indirect subsidiary or affiliate of Non-Party Boehringer

Ingelheim International GmbH. Collectively, these entities shall be referred to as "Boehringer Ingelheim" or "BI." BI was a manufacturer, distributor, and seller of brand OTC Zantac.

Sanofi

12. Non-Parties Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Patheon Manufacturing Services LLC, and Chattem, Inc. are U.S.-based companies that are direct or indirect subsidiaries or affiliates of Non-Party Sanofi SA, a French corporation. Collectively, these entities shall be referred to as "Sanofi." Non-Party Sanofi was a manufacturer, distributor, and seller of brand OTC Zantac.

C. Plaintiffs

13. Plaintiffs are individuals who purchased and used GSK's Zantac, as described below and *infra,* Section VI.

14. Plaintiff Golbenaz Bakhtiar (for the purpose of this paragraph, "Plaintiff") is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products in California while a citizen of California from approximately 2000 to December 2019 for acid reflux and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed up to twice daily, depending on her condition, with occasional gaps of no longer than a week: (a) 150 mg prescription Zantac tablets and capsules beginning in approximately 2000, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2000 to 2019 that were used interchangeably throughout the time period with the brand; (c) 150 mg OTC Zantac tablets and capsules from approximately 2000 until 2019, manufactured by Pfizer, BI, and Sanofi, when she needed an extra dose or ran out of her prescription; and (d) OTC 150 mg generic ranitidine tablets and capsules from approximately 2005 to 2019, when she needed an extra dose or ran out of her prescription. Thus, GSK is the

"Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

15. Plaintiff Felicia Ball (for the purpose of this paragraph, "Plaintiff") is a citizen of Pennsylvania. Plaintiff purchased and used Ranitidine-Containing Products in Pennsylvania while a citizen of Pennsylvania from approximately 2000 to 2020 for irritable bowel syndrome. The Ranitidine-Containing Products purchased and used by Plaintiff during that time specifically included the following, consumed at least once per day: (a) prescription Zantac in 150 mg and/or 300 mg manufactured by GSK beginning in 2000; and (b) prescription 150 mg and 300 mg generic ranitidine tablets and capsules when her insurance would not pay for brand Zantac. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

16. Plaintiff Teresa Dowler (for the purpose of this paragraph, "Plaintiff") is a citizen of Indiana. Plaintiff purchased and used Ranitidine-Containing Products from approximately 2011 to December 2019 in Indiana while a citizen of Indiana for GERD. The Ranitidine-Containing Products Plaintiff purchased and used daily specifically included (a) prescription 150 mg Zantac tablets and capsules from approximately 2011 to 2013, manufactured by GSK; (b) OTC 150 mg Zantac tablets and capsules from approximately 2013 to 2018 manufactured by BI and Sanofi; and (c) prescription 150 mg generic ranitidine tablets and capsules from approximately 2018 to December 2019. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

17. Plaintiff Jonathan Ferguson (for the purpose of this paragraph, "Plaintiff") is a citizen of Washington. Plaintiff purchased and used Ranitidine-Containing Products from approximately 1996 to 2017 for heartburn and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included the following, consumed daily: (a) OTC Zantac tablets and capsules in approximately 1996 and 1999 in Nevada while a citizen of Nevada, manufactured by GSK and Pfizer; (b) OTC Zantac tablets and capsules from approximately 2007 to 2012 in California while a citizen of California, manufactured by BI; and (c) OTC ranitidine tablets from 2010 to 2012 in California while a citizen of California. Thus, GSK is the

"Defendant" with respect to purchases made in Nevada while a citizen of Nevada, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

18. Plaintiff Michael Galloway (for the purpose of this paragraph, "Plaintiff") is a citizen of Ohio. Plaintiff purchased and used Ranitidine-Containing Products from approximately 1989 through October 2019 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed up to three times daily specifically included (a) prescription 150 mg Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida; (c) OTC Zantac tablets and capsules from approximately 1997 through 1999 in Florida while a citizen of Florida manufactured by GSK and Pfizer; (d) prescription 150 mg generic ranitidine tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio; (e) OTC Zantac tablets and capsules from approximately 1999 through October 2019 in Ohio while a citizen of Ohio manufactured by Pfizer, BI, and Sanofi; and (f) prescription 150 mg Zantac tablets and capsules, beginning in approximately 1999 in Ohio, manufactured by GSK. Plaintiff often supplemented his usage with 2 additional pills a day by using OTC. Thus, GSK is the "Defendant" with respect to purchases made in Florida while a citizen of Florida unless otherwise specified;

and GSK is the "Defendant" with respect to purchases made in Ohio while a citizen of Ohio unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

19. Plaintiff Alberta Griffin (for the purpose of this paragraph, "Plaintiff") is a citizen of Maryland. Plaintiff purchased and used Ranitidine-Containing Products in Maryland while a citizen of Maryland from approximately 2000 to March 2020 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff, consumed up to three times a day depending on her condition specifically included the following: (a) prescription Zantac tablets and capsules in increasing dosages beginning in approximately 2000, manufactured by GSK; (b) prescription 150 mg generic ranitidine tablets and capsules from approximately 2013 to March 2020 when her insurance would not pay for brand; and (c) OTC 150 mg Zantac tablets and capsules from approximately 2000 to March 2020, manufactured by Pfizer, BI, and Sanofi when she ran out of her prescription. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of

medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

20. Plaintiff Ronda Lockett (for the purpose of this paragraph, "Plaintiff") is a citizen of Texas. Plaintiff purchased and used Ranitidine-Containing Products from approximately 1983 to March 2020 for heartburn, acid reflux, and ulcers. The Ranitidine-Containing Products Plaintiff purchased and used in Missouri while a citizen of Missouri specifically included (a) prescription Zantac tablets and capsules consumed twice daily from approximately 1990 to 1995, which were manufactured by GSK; and (b) OTC Zantac tablets and capsules consumed once daily from approximately 1996 to 2000, which were manufactured by GSK and Pfizer. Thus, GSK is the "Defendant" with respect to purchases made in Missouri while a citizen of Missouri, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

21. Plaintiff Ricardo Moròn (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 1996 to 2020 for heartburn, acid reflux, and stomach discomfort. The Ranitidine-Containing Products purchased and used by Plaintiff specifically included 150 mg OTC Zantac tablets and capsules consumed approximately three to four times a week from approximately 1996 to 2020, which were manufactured by GSK, Pfizer, BI, and Sanofi. Thus,

GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

22. Plaintiff Richard Obrien (for the purpose of this paragraph, "Plaintiff") is a citizen of California. Plaintiff purchased and used Ranitidine-Containing Products in California while a citizen of California from approximately 1998 to November 2019 for gastritis and GERD. The Ranitidine-Containing Products purchased and used by Plaintiff, consumed twice per day from approximately 1998 to 2008, and consumed once per day from approximately 2008 to 2019, specifically included: (a) OTC 150 mg Zantac tablets and capsules manufactured by GSK, Pfizer, BI, and Sanofi; and (b) OTC 150 mg generic ranitidine tablets and capsules when he occasionally ran out of Zantac brand. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

23. Plaintiff Jeffrey Pisano (for the purpose of this paragraph, "Plaintiff") is a citizen of Colorado. Plaintiff purchased and used Ranitidine-Containing Products in Colorado while a citizen of Colorado from approximately 1998 to February 2020 for heartburn. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed twice per day but later consumed as needed specifically included (a) OTC 150 mg Zantac tablets and capsules from approximately 1998 to 2020, which were manufactured by GSK, Pfizer, BI, and Sanofi; (b) prescription 150 mg Zantac tablets and capsules from approximately 1998 to 2003, which were manufactured by GSK; and (c) prescription 150 mg generic ranitidine tablets and capsules from approximately 1998 to 2003. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

24. Plaintiff Michael Tomlinson (for the purpose of this paragraph, "Plaintiff") is a citizen of Florida. Plaintiff purchased and used Ranitidine-Containing Products in Florida while a citizen of Florida from approximately 2000 to November 2019 for acid reflux. The Ranitidine-Containing Products purchased and used by Plaintiff and consumed twice daily specifically included the following: (a) prescription 300 mg Zantac tablets and capsules beginning in 2000 and continuing through at least 2002, manufactured by GSK; (b) prescription 150 mg and 300 mg generic ranitidine tablets and capsules at some point thereafter until 2019; and (c) OTC 150 mg

Zantac tablets and capsules from approximately 2000 to 2019, manufactured by Pfizer, BI, and Sanofi when he ran out of or did not have access to his prescription. Thus, GSK is the "Defendant" for the purposes of Plaintiff's claims, unless otherwise specified. As a direct and proximate result of consuming GSK's Ranitidine-Containing Products, which were unsafe for human ingestion, Plaintiff is at a significantly increased risk for developing the Subject Cancers and is in need of regular monitoring. Plaintiff would not have consumed GSK's Ranitidine-Containing Products had Plaintiff known that doing so would subject Plaintiff to a significantly increased risk of developing the Subject Cancers, as well as the cost of medical monitoring and subsequent treatment. Thus, Plaintiff has suffered concrete injury as a result of GSK's wrongful conduct.

IV. FACTUAL ALLEGATIONS

A. THE CREATION OF RANITIDINE-CONTAINING PRODUCTS AND THEIR INTRODUCTION TO THE MARKET

25. GSK designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine under the brand Zantac by prescription and/or OTC.

1. GSK Develops Zantac Through a Flurry of Aggressive Marketing Maneuvers

26. Ranitidine belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (branded Tagamet), famotidine (Pepcid), and nizatidine (Axid).

27. GSK-predecessor Smith, Kline & French discovered and developed Tagamet, the first H_2 blocker and the prototypical histamine H_2 receptor antagonist from which the later members of the class were developed.

28. GSK[9] developed Zantac specifically in response to the success of cimetidine. Recognizing the extraordinary potential of having its own H_2 blocker in the burgeoning anti-ulcer market, GSK was all too willing to ensure its drug succeeded at all costs.

29. In 1976, scientist John Bradshaw, on behalf of GSK-predecessor Allen & Hanburys Ltd. synthesized and discovered ranitidine.

30. Allen & Hanburys Ltd., a then-subsidiary of Glaxo Laboratories Ltd., is credited with developing ranitidine and was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule.

31. In 1983, the FDA granted approval to GSK to sell Zantac, pursuant to the New Drug Application ("NDA") No. 18-703, and it quickly became GSK's most successful product—a "blockbuster." Indeed, Zantac became the first prescription drug in history to reach $1 billion in sales.

32. To accomplish this feat, GSK entered into a joint promotion agreement with Hoffmann-LaRoche, Inc., [redacted].[10] More salespersons drove more sales and blockbuster profits for GSK.

33. In June 1986, the FDA approved Zantac for maintenance therapy of duodenal ulcers and for treatment of patients with gastroesophageal reflux disease ("GERD").

34. In December 1993, GSK (through Glaxo Wellcome plc) entered into a partnership agreement with Pfizer-predecessor company Warner-Lambert Co. to develop and market an OTC

[9] GSK, as it is known today, was created through a series of mergers and acquisitions: In 1989, Smith, Kline & French merged with the Beecham Group to form SmithKline Beecham plc. In 1995, Glaxo merged with the Wellcome Foundation to become Glaxo Wellcome plc. In 2000, Glaxo Wellcome plc merged with SmithKline Beecham plc to form GlaxoSmithKline plc and GlaxoSmithKline LLC.

[10] GSKZAN0000348881; GSKZAN0000348871

version of Zantac.[11] In 1995, the FDA approved OTC Zantac 75 mg tablets through NDA 20-520. In 1998, the FDA approved OTC Zantac 75 mg effervescent tablets through NDA 20-745.

35. In 1998, GSK (Glaxo Wellcome plc) and Warner-Lambert Co. ended their partnership. As part of the separation, Warner-Lambert Co. retained control over the OTC NDA for Zantac and the Zantac trademark in the United States and Canada but was required to obtain approval from GSK prior to making any product or trademark improvements or changes. GSK retained rights to sell OTC Zantac outside of the United States and Canada,[12] and retained control over the Zantac trademark internationally.[13]

36. In 2000, Pfizer acquired Warner-Lambert Co. Pfizer controlled the Zantac OTC NDAs until December 2006.

37. In October 2000, GSK sold to Pfizer the full rights to OTC Zantac in the United States and Canada pursuant to a divestiture and transfer agreement. As part of that agreement, GSK divested all domestic Zantac OTC assets to Pfizer, including all trademark rights. The agreement removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription Ranitidine-Containing Product in the United States.

38. In October 2003, Pfizer submitted NDA 21-698 for approval to market OTC Zantac 150 mg. The FDA approved NDA 21-698 on August 31, 2004.

39. During the time that Pfizer owned the rights to OTC Zantac, GSK continued to manufacture the product.

[11] GSKZAN0000022775.
[12] GSK also still held the right to sell prescription Zantac in the United States.
[13] PFI00245109.

40. In 2006, pursuant to a Stock and Asset Purchase Agreement, Pfizer sold and divested its entire consumer health division (including employees and documents) to Johnson & Johnson ("J&J").[14] Because of antitrust issues, however, Zantac was transferred to Boehringer Ingelheim.

41. Pfizer, through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, research and development, and customer and supply contracts to Boehringer Ingelheim.

42. As part of that deal, Boehringer Ingelheim obtained control and responsibility over all of the Zantac OTC NDAs.

43. GSK continued marketing prescription Zantac in the United States until 2017 and still holds the NDAs for several prescription formulations of Zantac. GSK continued to maintain manufacturing and supply agreements relating to various formulations of both prescription and OTC Zantac. According to its recent annual report, GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 . . . in the U.S."[15]

44. Boehringer Ingelheim owned and controlled the NDA for OTC Zantac between December 2006 and January 2017, and manufactured, marketed, and distributed the drug in the United States during that period.[16]

45. In 2017, Boehringer Ingelheim sold the rights of OTC Zantac to Sanofi pursuant to an asset swap agreement. As part of that deal, Sanofi obtained control and responsibility over

[14] PFI00191352.
[15] GlaxoSmithKline, plc, *Annual Report* 37 (2019), https://www.gsk.com/media/5894/annual-report.pdf.
[16] Boehringer Ingelheim also owned and controlled ANDA 074662.

Boehringer Ingelheim's entire consumer healthcare business, including the OTC Zantac NDAs. As part of this agreement, Boehringer Ingelheim and Sanofi entered into a manufacturing agreement wherein Boehringer Ingelheim continued to manufacture OTC Zantac for Sanofi.

46. Sanofi has controlled the OTC Zantac NDAs and marketed, sold, and distributed Zantac in the United States from January 2017 until 2019 when it issued a global recall and ceased marketing, selling, and distributing OTC Zantac. In addition, Sanofi has marketed, sold, and distributed ranitidine globally since 1983.[17]

47. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

48. Sanofi voluntarily recalled all Brand OTC Zantac and ranitidine on October 18, 2019.

49. Pfizer and Boehringer Ingelheim have made demands for indemnification per the Stock and Asset Purchase Agreement against J&J for legal claims related to OTC Zantac products.

50. Sanofi has made a demand for indemnification against J&J pursuant to a 2016 Asset Purchase Agreement between J&J and Sanofi.

[17] SANOFI_ZAN_MDL_0000208478.

51. The times during which each Brand Manufacturer manufactured and/or sold branded Zantac are alleged below:

Manufacturer/ Repackager	Product	Prescription or Over the Counter	Sale Start Date Year	Sale End Date Year
GlaxoSmithKline	Pills, Syrup, and Injection	Prescription	1983	2019
GlaxoSmithKline	Pills	OTC	1996	2000
Pfizer	Pills	OTC	1998	2006
Boehringer Ingelheim	Pills	OTC	2007	2019
Sanofi	Pills	OTC	2017	2019

52. As recently as 2018, Zantac was one of the top 10 antacid tablets in the United States, with sales of OTC Zantac 150 totaling $128.9 million – a 3.1% increase from the previous year.

2. NDMA Is a Carcinogen Whose Dangerous Properties Are Well Established

53. According to the Environmental Protection Agency ("EPA"), NDMA is a semivolatile organic chemical that forms in both industrial and natural processes."[18] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. Scientists have long recognized the dangers that NDMA poses to human health. A 1979 news article noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[19] NDMA is no longer

[18] U.S. Environmental Protection Agency, *Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA)* (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[19] Jane Brody, *Bottoms Up: Alcohol in Moderation Can Extend Life*, The Globe & Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger Grows as Officials Unable to Trace Poison in Reserve's Water*, The Globe & Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA Adducts in Humans After Exposure to Methylating Agents*, 405 Mut. Res. 135 (1998) (noting that "chronic exposure of rats

produced or commercially used in the United States except for research. Its only use today is to cause cancer in laboratory animals.

54. Both the EPA and the International Agency for Research on Cancer ("IARC") classify NDMA as a probable human carcinogen.[20]

55. The IARC classification is based upon data that demonstrates NDMA "is carcinogenic in all animal species tested: mice, rats, Syrian gold, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, various fish, newts and frogs. It induces benign and malignant tumors following its administration by various routes, including ingestion and inhalation, in various organs in various species." Further, in 1978, IARC stated that NDMA "should be regarded for practical purposes as if it were carcinogenic to humans."[21]

56. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[22]

57. The Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[23] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.[24]

---

to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

[20] *See* EPA Technical Fact Sheet, *supra,* note 18; Int'l Agency for Research on Cancer (IARC), *Summaries & Evaluations, N-NITROSODIMETHYLAMINE* (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html.

[21] 17 Int'l Agency for Research on Cancer, *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Some N-Nitroso Compounds* 151–52 (May 1978).

[22] *See* EPA Technical Fact Sheet, *supra* note 18.

[23] *Id*. at 3.

[24] *Id*.

58. The FDA considers NDMA a carcinogenic impurity[25] and chemical that "could cause cancer" in humans.[26] The FDA recognizes that NDMA is "known to be toxic."[27]

59. The World Health Organization states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[28] NDMA belongs to the so-called "cohort of concern" which is a group of highly potent mutagenic carcinogens that have been classified as probable human carcinogens.[29]

60. NDMA is among the chemicals known to the State of California to cause cancer (Title 27, California Code of Regulations, Section 27001), pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

61. The European Medicines Agency "(EMA") has referred to NDMA as "highly carcinogenic." It recommended that "primary attention with respect to risk for patients should be on these highly carcinogenic N-nitrosamines" (including NDMA), and categorized NDMA as "of highest concern with respect to mutagenic and carcinogenic potential."[30]

---

[25] ApotexCorp_0000000786.

[26] FDA Statement, Janet Woodcock, Director – Ctr. for Drug Evaluation & Research, *Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine* (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[27] Amneal_prod 1 _ 0000002938.

[28] World Health Org., *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3d ed. 2008), https://www.who.int/water_sanitation_health/dwq/chemicals/ndmasummary_2ndadd.pdf.

[29] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk, M7(R1), March 2017; https://database.ich.org/sites/default/files/M7_R1_Guideline.pdf.

[30] Nitrosamines EMEA-H-A5(3)-1490 - Assessment Report (europa.eu) (June 25, 2020), https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-assessment-report_en.pdf.

62. In 1989, the Agency for Toxic Substances and Disease Registry (ATSDR) stated that it is "reasonable to expect that exposure to NDMA by eating, drinking or breathing could cause cancer in humans" and that the "carcinogenicity of orally administered NDMA has been demonstrated unequivocally in acute, intermediate and chronic durations studies" in animals and "it is important to recognize that this evidence also indicates that oral exposures of acute and intermediate duration are sufficient to induce cancer." Moreover, "hepatoxicity has been demonstrated in all animal species that have been tested and has been observed in humans who were exposed to NDMA by ingestion or inhalation." [31]

63. The International Register of Potentially Toxic Chemicals (IRPTC 1988) lists regulations imposed by 13 countries for NDMA for occupational exposure, packing, storing and transport, disposal, and warns of its probable human carcinogenicity and its high level of toxicity by ingestion or inhalation.

64. The Occupational Safety and Health Administration classifies NDMA as "a carcinogen" that requires special and significant precautions along with specific hazard warnings.[32]

65. A review of Defendant's own internal documents reveals that there is simply no question of material fact that it has been widely known within the medical and scientific community for over 40 years that NDMA is toxic and a known carcinogen.

66. In September 2019, Defendant GSK [redacted]

[31] ATSDR Toxicological Profile For N-Nitrosodimethylamine (December 1989), http://www.atsdr.cdc.gov/toxprofiles/tp141.pdf.

[32] 29 C.F.R §1910.1003 (2012).

[redacted][33] In addition, GSK [redacted] *Id.* GSK [redacted] *Id.*

67. [redacted][34] [redacted][35] [redacted][36]

68. [redacted]

[33] GSKZAN0000236640.
[34] GSKZAN0000369506.
[35] GSKZAN0000257640.
[36] *Id.*

[redacted][37] [redacted]

[redacted][38]

[redacted]

[redacted][39] [redacted]

[redacted]

[redacted]

[redacted][40]

69. Likewise, Sanofi [redacted]

[redacted][41] [redacted]

[redacted]

[redacted]

[redacted][42] [redacted]

[redacted] *Id*.

70. Non-Party Dr. Reddy's [redacted]

[redacted]

[redacted][43] [redacted]

[redacted]

[redacted]

[37] GSKZAN0000163882.
[38] *See* GSK Dear HCP Letter, (October 3, 2019), publicly available (for example, https://www. hpra. ie/docs/default-source/Safety-Notices/gsk-hcp-letter-03oct2019.pdf).
[39] GSKZAN0000178581.
[40] GSKZAN0000172037.
[41] SANOFI ZAN MDL 0000169790.
[42] SANOFI ZAN MDL 0000206858.
[43] DRLMDL0000077291.

[redacted][44] [redacted]

[redacted][45]

71. [redacted]

[redacted][46] [redacted] *Id*.

72. Non-Party Apotex [redacted]

[redacted][47]

73. Non-Party Glenmark admits in its recall notification letter that "a carcinogenic impurity, NDMA, has been found in ranitidine medications at levels exceeding the FDA allowable limit."[48]

74. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

[44] DRLMDL0000070414.
[45] *Id*.
[46] DRLMDL0000069991.
[47] ApotexCorp 0000030734.
[48] GiantEagle_MDL2924_00000303.

75. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure – Valsartan, Losartan, and Irbesartan – because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

76. This continued in 2020 when the FDA required recalls of numerous generic manufacturers' metformin, including metformin made by Apotex, Amneal, Granules, Sun Pharmaceuticals, Nostrum, and Teva.[49]

77. NDMA is a genotoxin which interacts with DNA and may subsequently induce mutations. Genotoxins are not considered to have a safe threshold or dose due to their ability to alter DNA.

78. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. That means that consumption of 96 ng of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 ng is considered unacceptable.[50]

79. In studies examining carcinogenicity through oral administration, mice exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, cancers were observed in the liver, pancreas, and stomach. In comparable guinea-pig studies, cancers were

[49] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Metformin* (Jan. 6, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

[50] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)* (Feb. 28, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

observed in the liver and lung. In comparable rabbit studies, cancers were observed in the liver and lung.

80. In other long-term animal studies in mice and rats utilizing different routes of exposures – inhalation, subcutaneous injection, and intraperitoneal (abdomen injection) – cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

81. Prior to the withdrawal of ranitidine, it was considered a category B drug for birth defects, meaning it was considered safe to take during pregnancy. Yet animals exposed to NDMA during pregnancy birthed offspring with elevated rates of cancer in the liver and kidneys.

82. NDMA is a very small molecule. That allows it to pass through the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

83. Exposure to high levels of NDMA has been linked to liver damage in humans.[51]

84. Numerous *in vitro* studies confirm that NDMA is a mutagen – causing genetic mutations in human and animal cells.

85. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice; rats; Syrian golden, Chinese and European hamsters; guinea pigs; rabbits; ducks; mastomys; fish; newts; and frogs.

86. The EPA classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."[52]

[51] *See* EPA Technical Fact Sheet, *supra* note 18.
[52] *Id.*

87. Pursuant to EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[53]

88. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. These studies consistently show increased risks of various cancers.

89. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 micrograms/day.[54]

90. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 micrograms/day.[55]

91. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at 0.179 micrograms/day.[56]

92. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "*N*-nitroso compounds are potent

[53] *See* U.S. Envtl. Protection Agency, Risk Assessment Forum, *Guidelines for Carcinogen Risk Assessment* (Mar. 2005), https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.
[54] Pobel et al., *Nitrosamine, Nitrate and Nitrite in Relation to Gastric Cancer: A Case-control Study in Marseille, France*, 11 Eur. J. Epidemiol. 67-73 (1995).
[55] La Vecchia, *et al*., *Nitrosamine Intake & Gastric Cancer Risk*, 4 Eur. J. Cancer Prev. 469-74 (1995).
[56] Rogers et al., *Consumption of Nitrate, Nitrite, and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cance*r, 5 Cancer Epidemiol. Biomarkers Prev. 29–36 (1995).

carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[57]

93. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, and pharynx cancer.[58]

94. In a 2011 epidemiological cohort study looking at NDMA dietary exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[59]

95. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 1,760 cases, researchers found a statistically significant elevated association between NDMA exposure and rectal cancer.[60]

96. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro*. However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the carcinogenicity of NDMA."[61]

---

[57] Knekt et al., *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 Int. J. Cancer 852–56 (1999).

[58] Straif et al., *Exposure to High Concentrations of Nitrosamines and Cancer Mortality Among a Cohort of Rubber Workers*, 57 Occup. Envtl. Med 180–87 (2000).

[59] Loh et al., *N-nitroso Compounds and Cancer Incidence: The European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 Am. J. Clinical Nutrition 1053–61 (2011).

[60] Zhu et al., *Dietary N-nitroso Compounds and Risk of Colorectal Cancer: A Case-control Study in Newfoundland and Labrador and Ontario, Canada*, 111 Brit. J. Nutrition 6, 1109–17 (2014).

[61] World Health Org., *supra* note 28.

97. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (a:) can exacerbate existing but dormant (*i.e.,* not malignant) tumor cells; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

3. NDMA Is Discovered in Ranitidine-Containing Products, Leading to Market Withdrawal

98. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all Ranitidine-Containing Products due to detecting exceedingly high levels of NDMA when testing ranitidine pills using gas chromatography-mass spectrometry. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[62] This set off a cascade of recalls by Zantac manufacturers.

99. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement warning that some ranitidine medicines may contain NDMA.[63]

[62] FDA Statement, Woodcock, *supra* note 26; Press Release, European Medicines Agency, *EMA to Review Ranitidine Medicines Following Detection of NDMA* (Sept. 13, 2019), https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

[63] FDA Statement, Woodcock, *supra* note 26.

100. On September 24, 2019, Sandoz voluntarily recalled all of its Ranitidine-Containing Products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."[64]

101. On September 26, 2019, Non-Parties Apotex, Walgreens, Walmart, and Rite Aid voluntarily recalled all ranitidine products and removed them from shelves.[65] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)."[66]

102. On September 28, 2019, Non-Party CVS stated that it would stop selling Zantac and its CVS Health Store-Brand ranitidine out of concern that it might contain a carcinogen.

103. On October 2, 2019, the FDA ordered manufacturers of ranitidine to test their products and recommended using a liquid chromatography with high resolution mass spectrometer ("LC-HRMS") testing protocol, which "does not use elevated temperatures."[67]

---

[64] FDA News Release, U.S. Food & Drug Admin., *FDA Announces Voluntary Recall of Sandoz Ranitidine Capsules Following Detection of an Impurity* (Sept. 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity.

[65] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Sept. 26, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[66] Company Announcement, U.S. Food & Drug Admin., *Apotex Corp. Issues Voluntary Nationwide Recall of Ranitidine Tablets 75mg and 150mg (All Pack Sizes and Formats) Due to the Potential for Detection of an Amount of Unexpected Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Sept. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and.

[67] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

104. On October 8, 2019, Defendant GSK voluntarily recalled all Ranitidine-Containing Products internationally.[68] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[69]

105. On October 18 and 23, 2019, Sanofi and generic manufacturer Dr. Reddy's voluntarily recalled all of their Ranitidine-Containing Products.[70]

106. On October 28, 2019, generic manufacturer Perrigo voluntarily recalled all of its Ranitidine-Containing Products.[71]

107. In its recall notice, Perrigo stated, "[a]fter regulatory bodies announced that ranitidine may potentially contain NDMA, Perrigo promptly began testing of its externally sourced ranitidine API (active pharmaceutical ingredient) and ranitidine-based products. On October 8, 2019, Perrigo halted shipments of the product based upon preliminary results. Based on the totality of data gathered to date, Perrigo has made the decision to conduct this voluntary recall."[72]

108. On November 1, 2019, the FDA announced the results of recent testing, finding unacceptable levels of NDMA in Ranitidine-Containing Products, and requested that drug makers

---

[68] Press Release, Gov. UK, *Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls All Unexpired Stock* (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[69] Justin George Varghese, *GSK Recalls Popular Heartburn Drug Zantac Globally After Cancer Scare*, Reuters (Oct. 8, 2019), https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[70] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Oct. 23, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[71] *Id*.

[72] Company Announcement, U.S. Food & Drug Admin., *Perrigo Company plc Issues Voluntary Worldwide Recall of Ranitidine Due to Possible Presence of Impurity, N-nitrosodimethylamine (NDMA) Impurity in the Product* (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-company-plc-issues-voluntary-worldwide-recall-ranitidine-due-possible-presence-impurity-n.

begin to voluntarily recall their Ranitidine-Containing Products if the FDA or manufacturers discovered NDMA levels above the acceptable limits.[73]

109. On December 4, 2019, the FDA issued a statement notifying consumers who wished to continue taking ranitidine to consider limiting their intake of nitrite-containing foods, *e.g.*, processed meats and preservatives like sodium nitrite.[74] This advice ***mirrored*** an admonition issued by Italian scientists in 1981 after finding that ranitidine reacted with nitrites *in vitro* to form toxic and mutagenic effects in bacteria. The prudent advice of Dr. Silvio de Flora published in October 1981 in *The Lancet* was to "avoid nitrosation as far as possible by, for example, suggesting a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals or by giving inhibitors of nitrosation such as ascorbic acid."[75] If GSK had only heeded Dr. de Flora's advice in 1981, millions of people might have avoided exposure to NDMA formed as a result of ranitidine's interaction with the human digestive system.

110. Between November 1, 2019, and February 27, 2020, generic manufacturers Amneal and Glenmark recalled their products from the market, citing NDMA concerns.[76]

111. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that the ranitidine molecule is heat-liable and under certain temperatures progressively accumulates NDMA.

---

[73] U.S. Food & Drug Admin., Laboratory Tests | Ranitidine, https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine (content current as of Nov. 1, 2019).

[74] U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* (Dec. 4, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[75] Silvio de Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, The Lancet, Oct. 31, 1981, at 993-94.

[76] *See generally* U.S. Food & Drug Admin., *FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)* https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (content current as of Apr. 16, 2020).

112. Emery's Citizen Petition outlined its substantial concern that ranitidine is a time- and temperature-sensitive pharmaceutical product that develops NDMA when exposed to heat, a common occurrence during shipping, handling, and storage. Emery requested that the FDA issue a directive to manufacturers to clearly label ranitidine with a warning that "by-products that are probable carcinogens can be generated if exposed to heat." In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles.[77]

113. In response,[78] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[79] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[80] The FDA found that the recall of all Ranitidine-Containing Products and a public warning of the recall was necessary because the "product being recalled presents a serious health risk."[81] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[82]

114. The FDA found its stability testing raised concerns that NDMA levels in some Ranitidine-Containing Products stored at room temperature can increase with time to unacceptable levels. In the same vein, FDA testing revealed that higher NDMA levels were found as the

[77] Emery Pharma FDA Citizen Petition (Jan. 2, 2020) https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.
[78] Letter of Janet Woodcock, U.S. Food & Drug Admin., Docket No. FDA-2020-P-0042 (Apr. 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.
[79] *Id*. at 5 (*citing* 21 CFR 7.40(a)).
[80] *Id*.
[81] *Id*. at 7.
[82] *Id*. at 10 n.43.

products approached their expiration dates. The FDA's testing eroded the agency's confidence that any Ranitidine-Containing Product would remain stable through its labeled expiration date. Consequently, the FDA requested a market withdrawal of all ranitidine products. The FDA also announced to the public that the Agency's laboratory tests indicate that temperature and time contribute to an increase in NDMA levels in some ranitidine products. The FDA's decision to withdraw the drug rendered moot Emery's request for temperature-controlled shipping conditions.

115. The FDA's reaction was consistent with comparable regulatory action throughout the world. Before the FDA acted, over 43 different countries and jurisdictions restricted or banned Ranitidine-Containing Products.[83]

116. The European Medicines Agency ("EMA"), the Union's EU equivalent to the FDA, through an Article 31 Referral, determined the sale of all Ranitidine-Containing Products should be suspended on September 19, 2019. On April 30, 2020, the Human Medicines Committee of the EMA "has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of an impurity called N-nitrosodimethylamine (NDMA)." The EMA recognizes NDMA as a probable human carcinogen and issued a "precautionary suspension of these medicines in the EU" because "NDMA has been found in several ranitidine medicines above levels considered acceptable, and there are unresolved questions about the source of the impurities."[84]

---

[83] Margaret Newkirk & Susan Berfield, *FDA Recalls Are Always Voluntary and Sometimes Haphazard – and The Agency Doesn't Want More Authority to Protect Consumers*, Bloomberg Businessweek (Dec. 3, 2019), https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

[84] Eur. Med. Agency, *Suspension of Ranitidine Medicines in the EU* (Apr. 30, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-suspension-ranitidine-medicines-eu_en.pdf.

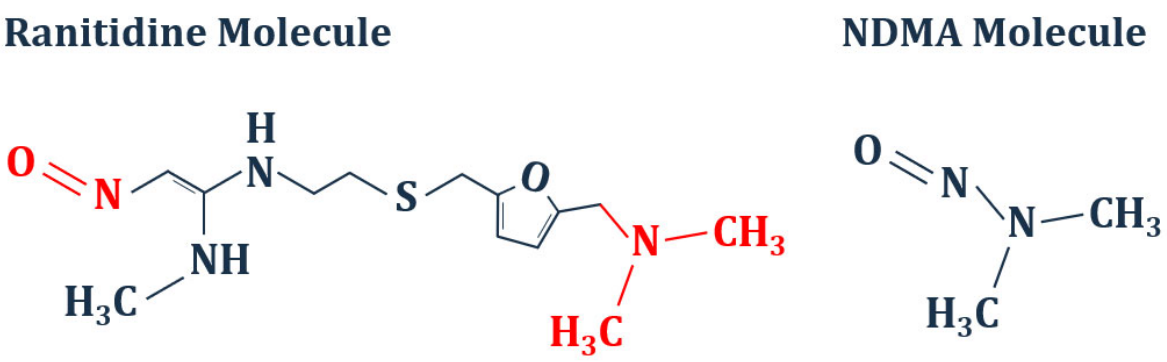
117. On September 17, 2020, after a ranitidine manufacturer requested that the EMA re-examine its decision and permit ranitidine to be marketed again in the EU, the EMA confirmed its prior recommendation to suspend all ranitidine medicines in the EU due to the presence of NDMA noting that it is a probable human carcinogen and that there is evidence that NDMA forms from the degradation of ranitidine itself with increasing levels seen over shelf life.[85]

B. THE SCIENCE

1. How Ranitidine Transforms into NDMA

118. The ranitidine molecule itself contains the constituent molecules to form NDMA. *See* Figure 1.

Figure 1 – Diagram of Ranitidine & NDMA Molecules



119. The degradation occurs independently in two parts of the ranitidine molecule, with the products of the degradation combining to produce NDMA.

120. The formation of NDMA by the reaction of DMA and a nitroso source (such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for

[85] Eur. Med. Agency, EMA Confirms Recommendation to Suspend All Ranitidine Medicines in the EU (Nov. 24, 2020), https://www.ema.europa.eu/en/documents/referral/ranitidine-article-31-referral-ema-confirms-recommendation-suspend-all-ranitidine-medicines-eu_en.pdf.

contamination of the U.S. water supply.[86] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater-treatment plants were specifically linked to the presence of ranitidine.[87]

121. The high levels of NDMA observed in Ranitidine-Containing Products are a function of various factors. The ranitidine molecule internally degrades to form NDMA. The degradation of ranitidine can increase over time under normal storage conditions, but more so with exposure to heat and/or humidity. Once in the body, ranitidine continues to degrade and can yield increasing levels of NDMA in the human digestive system, and when it interacts with nitrogenous products.

2. Formation of NDMA in the Environment of the Human Stomach

122. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

123. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, *The Lancet*. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects."[88] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the "formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in

[86] Ogawa et al., *Purification and Properties of a New Enzyme, NG, NG-dimethylarginine Dimethylaminohydrolase, from Rat Kidney*, 264 J. Bio. Chem. 17, 10205–209 (1989).
[87] Mitch et al., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 Env. Eng. Sci. 5, 389–404 (2003).
[88] De Flora, *supra* note 75.

the context of ranitidine ingestion, "it would seem prudent to . . . suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals."[89] *Id*.

124. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in *The Lancet*, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[90]

125. This response reflects GSK's reputation for "adopting the most combative, scorched-earth positions in defense of its brands."[91] The company has no compunctions against distorting objective science to maintain its lucrative monopoly franchises, and its egregious conduct surrounding Zantac is not some isolated incident.

126. GSK endangered patient health while reaping billions of dollars in profits from Paxil, Wellbutrin, and Avandia. As we now know, the company was involved in covering up scientific data, offering illegal kickbacks to prescribing physicians, intimidating witnesses, and defrauding Medicare to profit from these medicines. In the wake of Congressional hearings into the company's outrageous misbehavior,[92] GSK's actions resulted in a criminal investigation and the then-largest guilty plea by a pharmaceutical company for fraud and failure to report safety data

[89] This admonition came two years before the FDA approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* Ctr. for Drug Eval. & Research, *Approval Package* (June 8, 1998), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20520s1_Zantac.pdf. So GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

[90] R. T., Brittain et al., *Safety of Ranitidine*, *The Lancet* 1119 (Nov. 14, 1981).

[91] Jim Edwards, *GSK's Alleged Coverup of Bad Avandia Data: A Snapshot of Its Poisonous Corporate Culture*, Moneywatch (July 13, 2010) https://www.cbsnews.com/news/gsks-alleged-coverup-of-bad-avandia-data-a-snapshot-of-its-poisonous-corporate-culture/.

[92] *Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia*, Senate Comm. on Finance, 111th Cong.2d Sess. 1 (Comm. Print Jan. 2010).

in the country's history.[93] There is currently an open investigation of GSK and Sanofi being conducted by the Department of Justice relating to the failure to disclose to the federal government information about the potential presence of NDMA in Zantac.[94]

127. GSK attended an FDA Advisory Committee in May 1982 where its representative testified and presented evidence relating to the safety of Zantac, including the potential for ranitidine to form nitrosamines. However, GSK failed to disclose its new evidence relating to ranitidine and the formation of a nitrosamine, specifically the formation of NDMA.[95]

128. One month later, in June 1982, GSK submitted its draft Summary Basis of Approval and labeling for Zantac. Again, GSK failed to submit or otherwise disclose its new evidence relating to ranitidine and the formation of NMDA.[96]

129. In its submission to the FDA, GSK discussed its findings from internal studies performed in 1980 that ranitidine formed a different nitrosamine, n-nitroso-nitrolic acid, a potent

[93] U.S. Dep't of Justice, *GlaxoSmithKline to Please Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

[94] Sanofi, Half-Year Financial Report (2020), https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/en/investors/docs/2020_07_29_HY_financial_report_EN.pdf.

[95] GSKZAN0000050413.

[96] GSKZNDAA0000071900.

mutagen, but explained that these results had no "practical clinical significance"[97]:

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

130. In 1980 – before Zantac was approved by the FDA – GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[98] Remarkably, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of forming nitrosamines and, in turn, cancer, but then dismissed this risk because people were allegedly only expected to use Ranitidine-Containing Products for a short-term period:

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

131. GSK knew – and indeed specifically admitted – that ranitidine could react with nitrite in the human stomach to form nitrosamines and, at the same time, that long-term use of

[97] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

[98] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

ranitidine could lead to elevated levels of nitrite in the human stomach. GSK also knew, but did not disclose, that it had new evidence showing that NDMA was generated by ranitidine under certain conditions.

132. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[99] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was flawed. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded."[100] In other words, GSK intentionally engineered the study to exclude the very samples most likely to contain a dangerous carcinogen.

133. Given the above information that was disclosed relating to the nitrosation potential and formation of nitrosamines, it is shocking that GSK conducted an internal study to assess the formation of NDMA and found that ranitidine, when exposed to sodium nitrite, formed hundreds of thousands of nanograms of NDMA. The GSK study was never published or disclosed to the public.

134. In 1983, the same year GSK started marketing Zantac in the United States, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic

[99] Thomas et al., *Effects of One Year's Treatment with Ranitidine and of Truncal Vagotomy on Gastric Contents*, 6 Gut. Vol. 28, 726–38 (1987).
[100] *Id*.

effects (ability to harm DNA).[101] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

135. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[102] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine." Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures, such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

136. In addition, as multiple Zantac manufacturers have noted in internal documents and recent submissions to regulatory authorities, a mechanism for ranitidine to form NDMA [redacted] [103] Therefore, this potential mechanism was disregarded.

137. [redacted]

[101] Maura et al., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 Tox. Lttrs. 97-102 (1983).
[102] De Flora et al., *Genotoxicity of Nitrosated Ranitidine*, 4 Carcinogenesis 3, 255-60 (1983).
[103] SANOFI_ZAN_MDL-0000033849-SANOFI_ZAN_MDL_0000033891, at SANOFI_ZAN_MDL_0000033873.

[redacted][104]

138. However, in 1985 GSK [redacted][105] [redacted][106]

> (1%). The remainder of the administered dose is found in the stool [US Zantac Prescribing Information]. The furoic acid metabolite of ranitidine has been reported to be formed in rats [Eddershaw, 1996]. It would be predicted that formation of this metabolite may also result in the release of dimethylamine (DMA) which may be available to form NDMA on exposure to nitrite. However, in publications reporting metabolism data in humans [Carey, 1981; Martin, 1981; Martin, 1982] the furoic acid metabolite of ranitidine is not detected by the Total Ion Current (TIC) chromatography using HPLC-MS.

139. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the

[104] GSKZNDAA0000072103-GSKZNDAA0000072128.
[105] GSKZAN0000369313, [redacted]
[106] GSKZNDAA0000636549.

breakdown of ranitidine were proposed.[107] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water-treatment plants that supply many U.S. cities with water.

140. In 2002, researchers conducted a controlled study to evaluate the concentration of nitrosamines, including NDMA, in the gastric fluid and urine in children with gastritis before and after four to six weeks of treatment with ranitidine. The study reported statistically significant increases in the nitrosamine concentration, including NDMA, in the gastric juice and urine in 93.3% of children after taking ranitidine for only four weeks. The researchers noted that nitrosamines belong to the most potent known carcinogens and no organisms have been found that would be resistant to the harmful effects, that neoplastic lesions induced by nitroso compounds may develop in any organ, and that nitrosamines induced a wide spectrum of tumors in studies using animal models. In addition, the authors noted specifically that NDMA induced similar symptoms of acute poisoning in humans and animals. They advised that prophylactic measures to avoid nitrosamine formation include a diet high in fruits and inclusion of ascorbic acid as well as limiting intake of processed meat. The conclusion was that ranitidine should only be recommended in children after careful consideration.[108]

141. Despite the direct evidence that children taking ranitidine were being exposed to dangerously high levels of carcinogenic nitrosamines including NDMA, Defendant recklessly continued to market and promote Zantac and/or ranitidine as safe and effective for children.

---

[107] Le Roux et al., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 Envtl. Sci. Tech. 20, 11095-103 (2012).

[108] Krawczynski, et al. *Nitrosamines in Children with Chronic Gastritis*, Journal of the Polish Pediatric Society (GSKZAN0000235261).

142. Similarly, in 2016, researchers at Stanford University conducted an experiment on healthy adult volunteers. They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. The study reported that on average, the level of NDMA increased by 400 times, to approximately 47,000 ng. The only change during that 24-hour period was the consumption of ranitidine. In the study, the scientists further explained that previous studies have indicated a high metabolic conversion rate of NDMA, meaning it will be processed by the human body. This study showed that ranitidine generates NDMA in the human body.[109]

143. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory purposes. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

144. In its September 9, 2019, Citizen's Petition to the FDA, [110] Valisure disclosed as part of its testing of Ranitidine-Containing Products that in every lot tested there were exceedingly high levels of NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended

[109] Zeng et al., *Oral intake of Ranitidine Increases Urinary Excretion of N-nitrosodimethylamine*, 37 Carcinogenesis 625–34 (2016). While this study was recently retracted due to errors in its testing method, its publication put the Brand Manufacturers on notice that ranitidine forms NDMA, particularly when subjected to heat, posing a risk of harm to those who consume it, and thus should have prompted them to conduct thorough research and analysis on that issue (including testing their pills using gas chromatography-mass spectrometry).

[110] Valisure, *Citizen Petition on Ranitidine* (Sept. 9, 2019), *available at* https://www.valisure.com/wp-content/uploads/Valisure-Ranitidine-FDA-Citizen-Petition-v4.12.pdf.

GC/MS headspace analysis method FY19-005-DPA for the determination of NDMA levels. As per the FDA protocol, this method was validated to a lower limit of detection of 25 ng.[111] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol

150 mg Tablets or equivalent	**Lot #**	**NDMA per tablet (ng)**
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

145. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under higher temperatures.

146. Valisure was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

[111] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

147. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF": 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF": 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

148. Indeed, Ranitidine-Containing Products were specifically advertised to be used when consuming foods containing high levels of nitrates, such as tacos or pizza.[112]

149. The results of Valisure's tests on ranitidine tablets in biologically relevant conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present, demonstrating proof of concept. (*see* Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation

Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid ("SIF")	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

[112] *See, e.g.*, Zantac television commercial, *Family Taco Night*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; Zantac television commercial, *Spicy*, https://youtu.be/jzS2kuB5_wg; Zantac television commercial, *Heartburn,* https://youtu.be/Z3QMwkSUlEg; Zantac television commercial, *Zantac Heartburn Challenge*, https://youtu.be/qvh9gyWqQns.

150. Following the release of Valisure Citizen's Petition, the FDA conducted additional laboratory tests, which showed NDMA levels in all ranitidine samples it tested, including API and the finished drug, both tablets and syrup. The FDA developed SGF and SIF models to use with the LC-MS testing method to estimate the biological significance of *in vitro* findings. These models are intended to detect the formation of NDMA in systems that approximate the stomach and intestine.

151. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine already containing NDMA combined with the presence of human-relevant levels of nitrite in the stomach – a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month – the ranitidine molecule transforms into more NDMA which would dramatically increase a person's risk of developing cancer.

3. Formation of NDMA in Other Organs of the Human Body

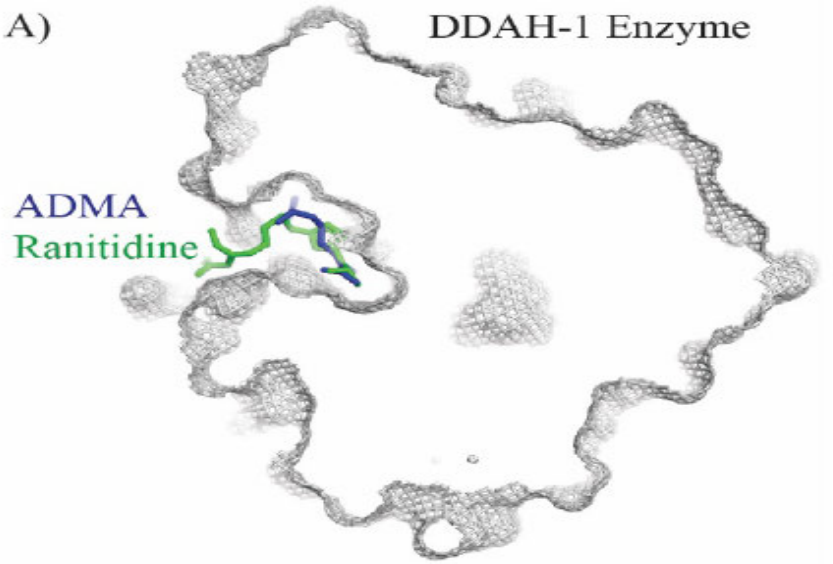
152. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

153. Valisure explained that liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful

knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[113]

154. Valisure reported as illustrated in Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme



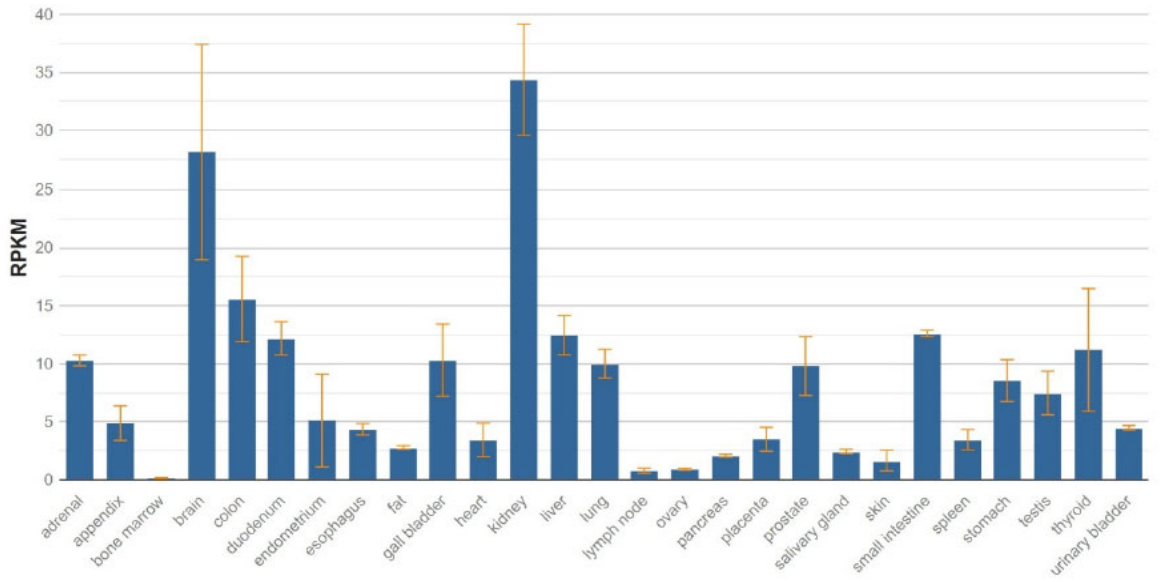
	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

155. Valisure reported that these results suggest that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

[113] Ogawa, *et al.*, *supra* note 86.

156. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



157. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the brain, colon, liver, small intestine, stomach, bladder, and prostate. Valisure noted that this offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs.

158. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study, discussed above.

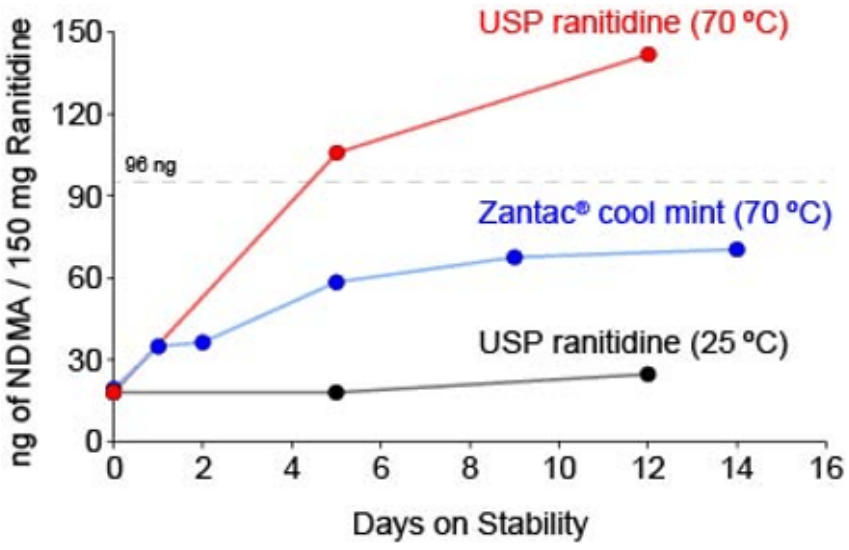
4. Formation of NDMA by Exposure to Heat, Moisture, and/or Time

159. The risk of creating NDMA by exposing ranitidine to heat has been well-known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that nitrosamines were formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which initially used a high heat testing method.

160. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

161. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine. The researchers exposed ranitidine to 70 ◦C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. As reported by Emery Pharma, the following diagram reveals how NDMA accumulates over time when exposed to 70 ◦C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



162. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.[114]

163. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat or humidity, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering Ranitidine-Containing Products have an approved shelf life of 36 months, the possibility of the drug accumulating dangerously high levels of NDMA prior to consumption is very real – a point underscored by the FDA's swift removal of the product from the market.

164. In fact, the FDA acknowledged that testing revealed that NDMA levels in ranitidine products stored at room temperature can increase with time to unacceptable levels.[115]

165. In 2019, the findings by Valisure unleashed an avalanche of regulatory authorities throughout the world demanding that the manufacturers of Zantac and/or ranitidine conduct testing of their products for the presence of NDMA as well as investigate the root cause as to how NDMA was being generated. In April 2020, the FDA requested that manufacturers immediately remove all Ranitidine-Containing Products from the market.

166. In the interim between the Valisure findings being released to the public and the FDA announcement requesting recall of all ranitidine products in April 2020, the manufacturers were investigating the root cause of NDMA in their products.

---

[114] Emery Pharma, *Emery Pharma Ranitidine: FDA Citizen Petition* (Jan. 2, 2020), *available at* https://emerypharma.com/news/emery-pharma-ranitidine-fda-citizen-petition/.
[115] Woodcock Letter, *supra* note 78.

167. After undertaking an investigation, GSK concluded that "the presence of NDMA in ranitidine drug substance is due to a slow degradation reaction occurring primarily in the solid state. The two constituent parts of NDMA, the nitroso group and the dimethylamino group, are both derived from internal degradation reactions which occur at slow rates with the ranitidine molecule."[116] Unsurprisingly, GSK [redacted] [117] In addition, GSK's testing revealed [redacted] [118]

168. Similarly, [redacted] [119]

169. [redacted] [120]

170. The FDA's own testing found that ranitidine sold by Sanofi contained up to 360 ng of NDMA per 150 mg tablet—3 times the ADI[121] in just one dose—and Plaintiffs frequently took

[116] GSKZAN0000052019-GSKZAN0000052127
[117] *Id*. p. 2.
[118] *Id*. p. 12.
[119] SANOFI_ZAN_MDL_0000151458
[120] SANOFI_ZAN_MDL_0000166517-527, at p. 11.
[121] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine. 1 microgram = 1000 nanograms.

more than one dose a day.

171. [redacted][122] [redacted]

[redacted][123]

172. Manufacturers could dictate the conditions under which API was transported to them. The labeling requirements do not apply to transporting API, in part because the finished product and API are packaged differently and may degrade under different conditions.

173. Based upon the documents produced by the Brand Manufacturers and based upon further information and belief, the Brand Manufacturers failed to ensure that their Ranitidine-Containing Products (in both API and finished dose form) were kept safely from excessive heat and humidity.[124]

5. Evidence Directly Links Ranitidine to Cancer

174. There are numerous studies, including epidemiological studies, that support the conclusion that NDMA and, specifically, NDMA in ranitidine, causes cancer in humans, including the Subject Cancers.

---

[122] GSKAN0000883508. Discovery is ongoing and it is anticipated that further information will be provided via expert reports and testimony.

[123] *See, e.g.*, SANOFI_ZAN_MDL_0000038689.

[124] *See, e.g.*, BOE_ZAN_MDL_0000203482 [redacted] GSKZAN0000178835 [redacted] DRLMDL0000087754 [redacted] DRLMDL0000077957 [redacted]

175. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[125] Similarly, a more recent study revealed that individuals who consumed ranitidine have a 22% increase in bladder cancer as compared with non-users.[126]

176. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.[127]

177. In another epidemiological study looking at various cancer risks and histamine H_2-receptor antagonists (or H_2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer. Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling of the risk of pancreatic cancer with ranitidine use.[128]

178. A study published in 2018 demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H_2 blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is

[125] D. Michaud et al., *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 Cancer Epi. Biomarkers & Prevention 250-54 (Feb. 2004).
[126] Cardwell, C. R., R. D. McDowell, C. M. Hughes, B. Hicks, and P. Murchie. *Exposure to Ranitidine and Risk of Bladder Cancer: A Nested Case-Control Study.* Am J Gastroenterol. 2021.
[127] Robert W. Mathes et al., *Relationship Between Histamine2-receptor Antagonist Medications and Risk of Invasive Breast Cancer*, 17 Cancer Epi. Biomarkers & Prevention 1, 67-72 (2008).
[128] Laurel A Habel et al., *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 Pharmacoepidemiology & Drug Safety 149–55 (2000).

particularly notable as the authors adjusted for variables.[129]

179. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H_2 blockers.[130] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H_2 blockers as a confounder. The study only considered use of H_2 blockers within one year of cancer diagnosis and still found an increased odds ratio associated with use of H_2 blockers and hepatocellular carcinoma, a type of liver cancer.

180. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[131] These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[132]

181. Moreover, a 2015 meta-analysis demonstrated a 34% increased risk of gastric cancer when individuals consumed 190 ng to 270 ng of NDMA a day.[133] A 1998 study illustrates

---

[129] Kim Tu Tran et al., *Proton Pump Inhibitor and Histamine-2 receptor Antagonist Use and Risk of Liver Cancer in Two Population-based Studies*, 48 Alimentary Pharmacology & Therapeutics 1, 55-64 (2018).

[130] Y-H J Shao et al., *Association Between Proton Pump Inhibitors and the Risk of Hepatocellular Carcinoma*, 48 Alimentary Pharmacology & Therapeutics 4, 460-68 (2018).

[131] Mathes et al., *supra* note 127; *see also* Jeong Soo Ahn et al., *Acid Suppressive Drugs and Gastric Cancer: A Meta-analysis of Observational Studies*, 19 World J. Gastroenterology 16, 2560 (2013); Shih-Wei Lai et al., *Use of Proton Pump Inhibitors Correlates with Increased Risk of Pancreatic Cancer: A Case-control Study in Taiwan*, 46 Kuwait Med J. 1, 44-48 (2014); Poulsen et al., *Proton Pump Inhibitors and Risk of Gastric Cancer – A Population Based Cohort Study*, 100 Brit. J. Cancer 1503-07 (2009); E Wennerström, *Acid-suppressing Therapies and Subsite-specific Risk of Stomach Cancer*, 116 Brit. J. Cancer 9, 1234–38 (2017).

[132] Richard H. Adamson & Bruce A. Chabne, *The Finding of N-Nitrosodimethylamine in Common Medicines,* The Oncologist, June 2020; 25(6): 460-62, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7288647/

[133] Song, et al. *Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis,* 7 Nutrients 9872-9895 (2015).

that with a daily intake of 270ng of NDMA, the risk of lung cancer is significantly increased.[134] And a 2011 study showed that there is a 46% increased risk of rectal cancer when 130 ng of NDMA are consumed a day.[135]

182. In addition to studies demonstrating that NDMA and, specifically, NDMA in ranitidine, directly causes cancer, research shows that exposure to NDMA (a) can exacerbate existing but dormant (*i.e.,* not malignant) tumor cells; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

C. DEFENDANT'S KNOWLEDGE OF THE NDMA RISK

183. As early as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested.[136] This was known or should have been known by each Brand Manufacturer as the information was available in medical literature.

184. In 1981, GSK, the originator of the ranitidine molecule, published a study focusing on the metabolites of ranitidine in urine using liquid chromatography.[137] Many metabolites were listed, though there is no indication that the study looked for NDMA.

185. Indeed, in that same year, Dr. de Flora published a note discussing the results of his experiments showing that ranitidine was turning into mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found

---

[134] DeStefani, et al., *Dietary Nitrosodimethylamine and the Risk of Lung Cancer: A Case Control Study from Uruguay,* 5 Cancer Epidemiology, Biomarkers & Prevention 670682 (Sept. 1996).
[135] Loh, et al., *supra* note 59.
[136] *See supra* ¶¶ 109, 123 (discussing de Flora research).
[137] Carey et al., *Determination of Ranitidine and Its Metabolites in Human Urine by Reversed-phase Ion-pair High-performance Liquid Chromatography*, 255 J. Chromatography B: Biomedical Sci. & Appl. 1, 161-68 (1981).

in food and in the body.[138] GSK was aware of this study because GSK specifically responded to the note and attempted to discredit it. The Brand Manufacturers knew or should have known about this scientific exchange as it was published in a popular scientific journal. The Brand Manufacturers were obligated to investigate this issue properly. None did.

186. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[139] That study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). But the study was flawed. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Not only is that approach not accurate, but GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." Without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. The inadequacy of that test was knowable in light of its scientific publication in 1987.

187. GSK either knew or should have known about the inadequacy of that study and should have investigated the issue properly and/or taken action to protect consumers from the NDMA risks in its products, but it did not.

D. THE FEDERAL REGULATORY LANDSCAPE

188. Plaintiffs reference federal law herein not in any attempt to enforce it, but only to demonstrate that their state-law tort claims do not impose any additional obligations on GSK,

[138] De Flora, *supra* note 75.
[139] Thomas et al., *supra* note 99.

beyond what is already required of it under federal law.

1. Federal Law Required GSK to Notify the FDA about the Presence of NDMA in Ranitidine-Containing Products

189. During the time that GSK manufactured and sold Ranitidine-Containing Products in the United States, the weight of scientific evidence showed that ranitidine exposed users to unsafe levels of NDMA. GSK failed to report these risks to the FDA.

190. GSK concealed the ranitidine–NDMA link from ordinary consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like ranitidine to the agency's attention.

191. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. §314.81(b)(2):

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

192. Title 21 C.F.R. §314.81(b)(2)(v) provides that the manufacturer's annual report must also contain:

> Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

193. GSK ignored these regulations and, disregarding the scientific evidence available to them regarding the presence of NDMA in its products and the risks associated with NDMA, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-

Containing Products.

194. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature such that any manufacturer, consistent with its heightened obligations to ensure the safety of its products, also should have known about the potential NDMA risks associated with ranitidine consumption.

195. GSK never conducted or provided the relevant studies to the FDA, nor did it present the FDA with a proposed disclosure noting the various ways that ranitidine transforms into NDMA. Accordingly, because GSK never properly disclosed the risks to the FDA, it never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

196. When the FDA eventually learned about the NDMA risks posed by Ranitidine-Containing Products, it ordered manufacturers to voluntarily remove the products from the market.

2. Good Manufacturing Practices

197. Under federal law, a manufacturer must manufacture, store, warehouse, and distribute pharmaceutical drugs in accordance with "Current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards.[140]

198. Title 21 C.F.R. §210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." Entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

[140] 21 U.S.C. §351(a)(2)(B).

199. Pursuant to 21 C.F.R. §211.142(b), the warehousing of drug products shall provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, GSK had a duty and was obligated to properly store, handle, and warehouse ranitidine.

200. Based on the above, GSK had a duty and were obligated to ensure that its ranitidine was properly stored, handled, and warehoused by it and its suppliers.

201. Testing conducted by the FDA confirms that under accelerated conditions the elevated temperatures can lead to the presence of NDMA in the drug product.[141] FDA has also concluded that NDMA can increase in ranitidine under storage conditions allowed by the labels, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during normal distribution and handling.

202. FDA's testing also showed that the level of NDMA in Ranitidine-Containing Products increases with time. And, while Emery's Citizen Petition sought to obtain a directive regarding temperature-controlled shipping of ranitidine, which was necessary given the time and temperature sensitivity of the drug, that request was deemed moot by the FDA because the agency sought to withdraw Ranitidine-Containing Products altogether.

203. Nothing prevented GSK from, on its own, taking actions to prevent accumulation of NDMA in Zantac by ensuring that ranitidine was not exposed to heat or moisture over long periods and by ensuring storage and transport at the lower end of the temperature range contained on the labels.

204. Based on the public scientific information, GSK knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human

[141] FDA Statement, Woodcock, *supra* note 26

stomach, and/or over time in storage.

205. At no time did GSK change the Zantac label to shorten the expiration date.

206. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

207. GSK knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

208. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

E. DEFENDANT'S TORTIOUS CONDUCT IN LABELING

1. Prescription Manufacturer GSK's Failure to Warn and Misrepresentations in the Labeling of Ranitidine-Containing Products

209. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) FALSE OR MISLEADING LABEL
>
> (1) If its labeling is false or misleading in any particular.

210. GSK was required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[142] and conform to requirements governing the appearance of the label.[143]

211. "Labeling" encompasses all written, printed, or graphic material accompanying the

[142] 21 C.F.R. §201.5.
[143] *Id.* §201.15.

drug or device,[144] and, therefore, broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

212. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[145]

213. GSK was responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products."[146] Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."[147]

214. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates."[148] And, expiration dates, in turn, must be set to "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use."[149] An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."[150]

215. Notably, while generic medications must have the same active ingredients as their

---

[144] *Id.*; 65 Fed. Reg. 14286 (Mar. 16, 2000).
[145] *United States v. Research Labs.*, 126 F.2d 42, 45 (9th Cir. 1942).
[146] 21 C.F.R. §211.166(a).
[147] *Id.*
[148] *Id.*
[149] *Id.*, §211.137(a).
[150] *Id.*, §211.137(b).

branded counterparts, the inactive ingredients, or excipients, may not necessarily be identical. For this reason, the stability of each generic drug may differ from manufacturer to manufacturer, or even from manufacturing process to manufacturing process.

216. GSK was required to conduct its own tests to determine and set accurate retest or expiration dates.

217. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."[151]

218. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."[152]

219. After a drug is approved, a manufacturer (brand or generic) can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.[153]

220. Some of the requirements in those regulations require a brand or generic

[151] 43 Fed. Reg. 45059 (Sept. 29, 1978).
[152] 21 C.F.R. §211.166(b).
[153] *See id.*, §314.97(a) (requiring generics to comply with §§314.70, 314.71).

manufacturer of an approved drug to obtain FDA approval before implementing a label change.[154]

221. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.[155]

222. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess."[156] "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."[157]

223. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date – which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"[158] – or to ensure that the drug is shipped and stored under appropriate conditions.

224. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or

[154] *Id.*, §314.70(b).
[155] *Id.*, §314.70(c)(3), (c)(6).
[156] *Id.*, §314.70(c)(6)(i).
[157] 65 Fed. Reg. 83042 (Dec. 29, 2000).
[158] 21 C.F.R. §211.137(a).

claims for effectiveness."[159]

225. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."[160]

226. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."[161]

227. At no time did GSK attempt to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

228. At no time did GSK attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

229. Based on the public scientific information, GSK knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

230. At no time did GSK change its label to shorten the expiration date. GSK had the

[159] *Id.*, §314.70(c)(6)(iii)(A), (C), (D).
[160] *Id.*, §314.70 (d)(2)(ix).
[161] *Id.*, §314.70 (d)(2)(vi); *see also id.*, §314.70(d)(2)(vii), (x).

ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had any Manufacturer Defendant attempted such label changes, the FDA would not have rejected them.

231. Because it failed to include appropriate expiration dates on its products, GSK failed to warn regarding and made false statements in the labeling of its products.

232. Because it failed to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months, GSK failed to warn regarding and made false statements in the labeling of its products.

2. GSK's Failure to Warn and Misrepresentations in the Labeling of OTC Ranitidine-Containing Products

233. GSK increased OTC Ranitidine–Containing Product demand through a fundamental and uniform message, parlayed through a multi-media campaign that OTC Zantac is safe, it can be used frequently, long-term, with high-nitrate and -nitrite foods, and poses no serious health risks such as those associated with the consumption of NDMA—a known human carcinogen.

234. Examples of this campaign include a series of television, print, radio, and internet ads for OTC Zantac throughout the United States and to consumers that uniformly omitted the material safety risks that the products contained NDMA, that ranitidine was instable, that NDMA content could increase through the lapse of time and when exposed to heat or humidity, and that it should not be used in connection with high-nitrate or -nitrite foods.

235. At the point of sale, GSK sold Zantac packaged and labeled with misleading information and material omissions.

236. Title 21 U.S.C. §352(a)(1) provides, in pertinent part,

> A drug or device shall be deemed to be misbranded –
>
> (a) False or misleading label
>
> (1) If its labeling is false or misleading in any particular.

237. GSK was required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label.

238. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, and, therefore, broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

239. "Most, if not all, labeling is advertising. The term 'labeling' is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."

240. GSK was also responsible for conducting stability testing, which must be "designed to assess the stability characteristics of drug products." Manufacturers must adopt a written testing program that includes: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; (4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed; (5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted."

241. The purpose of stability testing is, in part, to determine the "appropriate storage conditions and expiration dates." And, expiration dates, in turn, must be set to "assure that a drug

product meets applicable standards of identity, strength, quality, and purity at the time of use." An expiration date is "related to any storage conditions stated on the labeling, as determined by stability studies listed in §211.166."

242. Each Brand OTC Manufacturer such as GSK must conduct its own tests to determine and set accurate retest or expiration dates.

243. The FDA made clear when it first adopted the expiration-date provision that the regulation means what it says. The purpose of the expiration date is not merely to consider the "stability of a specific active ingredient." Instead, a compliant expiration date must account for multiple factors, including "the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use."

244. The FDA expressly recognizes that an initial expiration date may not be the final expiration date: "Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted . . . until the tentative expiration date is verified or the appropriate expiration date determined."

245. After a drug is approved, a brand manufacturer can make changes to its drug application. To do so, manufacturers must comply with the requirements of §§314.70 and 314.71.

246. Some of the requirements in those regulations require a brand manufacturer of an approved drug to obtain FDA approval before implementing a label change.

247. But the FDA has long recognized a "changes being effected" ("CBE") supplement that permits a manufacturer to make immediate changes, subject to FDA's post-change review.

248. A manufacturer of an approved drug can use the CBE supplement to immediately make an "[a]ddition to a specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength quality, purity, or potency that it purports or is represented to possess." "A specification is defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described."

249. A manufacturer, therefore, need not seek FDA pre-approval to make changes to its stability studies to identify the appropriate expiration date – which must "assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use"—or to ensure that the drug is shipped and stored under appropriate conditions.

250. A manufacturer of an approved drug can also use the CBE supplement to make changes "in the labeling to reflect newly acquired information" in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under §201.57(c) of this chapter"; "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product"; and "delete false, misleading, or unsupported indications for use or claims for effectiveness."

251. A manufacturer of an approved drug may make minor changes to a label with no approval or notice, so long as that change is described in an annual report. The illustrative but non-exhaustive list of minor changes includes "[a] change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form."

252. A "minor change" further includes "[a]n extension of an expiration dating period based upon full shelf life data on production batches obtained from a protocol approved in the NDA."

253. At no time did GSK attempt to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-nitrite foods; and (iv) consumed daily for a period of greater than a few months. The FDA never rejected such cancer warnings.

254. At no time did GSK attempt to change its label to delete a false or misleading expiration date, or to add a proper expiration date to ensure that Ranitidine-Containing Products would not break down into NDMA prior to human consumption.

255. Based on the public scientific information, GSK knew or should have known that NDMA could form in ranitidine by exposure to heat, humidity, nitrites, the conditions of the human stomach, and/or over time in storage.

256. At no time did GSK change its label to shorten the expiration date. GSK had the ability to unilaterally make such label changes (for both prescription and OTC) without prior FDA approval pursuant to the CBE regulation. Had GSK attempted such label changes, the FDA would not have rejected them.

257. Because it failed to include appropriate expiration dates on its products, GSK failed to warn regarding and made false statements in the labeling of its products.

258. Because it failed to include a warning on the labels for Ranitidine-Containing Products that consumers were at elevated risk of developing cancer if the products were: (i) exposed to excessive heat; (ii) exposed to excessive moisture/humidity; (iii) consumed with high-

nitrite foods; and (iv) consumed daily for a period of greater than a few months, GSK failed to warn regarding and made false statements in the labeling of its products.

V. ADDITIONAL COUNT-SPECIFIC ALLEGATIONS

A. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR FAILURE TO WARN THROUGH WARNINGS AND PRECAUTIONS

259. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; and (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

260. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

261. To mitigate degradation of ranitidine into NDMA in the stomach, consumers should have been warned not to take ranitidine with or after meals or in combination with a high-nitrite diet. No Ranitidine-Containing Product contained this warning.

262. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers could have been and should have been warned to consume ranitidine shortly after manufacturing and to store it in a cool, dry place (e.g., not in a bathroom). No Ranitidine-Containing Product contained this warning.

263. To mitigate the risk of NDMA causing cancer, consumers should have been warned to consume ranitidine for only short periods of time. No Ranitidine-Containing Product warned that cancer could result from long-term ingestion of ranitidine.

264. Defendant knew or should have known about each of these risks in time to warn consumers.

265. As was alleged in more detail above, in 1981 Dr. de Flora published the results of experiments in The Lancet showing that ranitidine produced NDMA in combination with gastric fluid and nitrites. This study put all future manufacturers of ranitidine on notice of the risks of consuming ranitidine in combination with high-nitrite foods.

266. GSK responded in The Lancet in November 1981. This response shows that GSK was in fact aware of Dr. de Flora's research.

267. GSK told the FDA that Dr. de Flora's research has no "practical clinical significance."

268. GSK conducted another study around 1981 that found that ranitidine could cause nitrates to convert into nitrites in the human stomach, which, in combination with Dr. de Flora's research, would mean a heightened risk of NDMA formation. This should have sparked reconsideration of the claim that nitrites would not be high enough in the stomach for Dr. de Flora's research to have practical significance.

269. In April 1982, GSK performed a study [redacted]

270. After Zantac had been approved for marketing by the FDA, GSK conducted a study on how ranitidine breaks down in the human stomach and concluded that the amount of nitrosamines formed was low. That study was published in 1987. However, GSK used a less reliable test (a nitrogen oxide assay) designed for use in food and discarded two-thirds of the

samples because they contained ranitidine (which the study claimed might produce a false positive).

271. In 1983, after GSK's flawed study, but before it was published, a University of Genoa study determined that ranitidine could react with nitrite and produce NDMA, which could induce DNA damage.

272. Also in 1983, Dr. de Flora published his complete findings, confirming his initial results about the risks of NDMA breakdown in the human stomach in combination with nitrites. GSK did not modify its position.

273. In 2002, a study indicated that NDMA was found in the urine and gastric fluid of children after taking ranitidine for four weeks.

274. In 2012, a study indicated that ranitidine may be a source of NDMA in drinking water.

275. In 2016, a Stanford University study suggested that NDMA amounts in humans increased after consuming ranitidine.

276. In 2019, Valisure tested ranitidine tablets to determine if they contained NDMA. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol developed for Valsartan, this method was validated to a lower limit of detection of 25 ng.[162] Valisure found when using the GC/MS headspace analysis method that ranitidine would transform into high levels of NDMA.

[162] U.S. Food & Drug Admin., *Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, FY19-005-DPA-S* (Jan. 28, 2019).

277. This testing by GC-MS demonstrates the instability of the ranitidine molecule and its propensity to break down under high temperatures.

278. Any Brand Manufacturer could have studied ranitidine using the tests Valisure performed, and would have discovered that ranitidine transforms into NDMA when subjected to heat.

279. At all relevant times, GSK designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA. These actions were under the ultimate control and supervision of GSK.

280. GSK designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, sold, and/or otherwise released into the stream of commerce their Ranitidine-Containing Products, and in the course of the same, directly marketed the products to consumers and end users, including Plaintiffs, and, therefore, had a duty to warn of the risks associated with the use of ranitidine.

281. At all relevant times, GSK had a duty to properly manufacture, test, market, label, package, handle, distribute, store, sell, provide proper warnings, and/or take such steps as necessary to ensure their Ranitidine-Containing Products did not cause users and consumers to suffer from unreasonable and dangerous risks. GSK had a continuing duty to warn Plaintiffs of dangers associated with ranitidine. GSK, as a manufacturer and seller of pharmaceutical medication, is held to the knowledge of an expert in the field.

282. GSK had a continuing duty to provide appropriate and accurate warnings and precautions.

283. At the time of manufacture, GSK could have provided warnings or instructions regarding the full and complete risks of ranitidine because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

284. At all relevant times, GSK failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of its products and to those who would foreseeably use or be harmed by GSK's Ranitidine-Containing Products.

285. Even though GSK knew or should have known that ranitidine posed a grave risk of harm, it failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to Ranitidine-Containing Products. The dangerous propensities of Ranitidine-Containing Products and the carcinogenic characteristics of NDMA, as described above, were known to GSK, or scientifically knowable to GSK through appropriate research and testing by known methods, at the time it distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

286. GSK knew or should have known that Ranitidine-Containing Products created significant risks of serious bodily harm to consumers, as alleged herein, and GSK failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and physicians of the risks of exposure to Ranitidine-Containing Products. GSK failed to warn and has wrongfully concealed information concerning the dangerous level of NDMA in Ranitidine-Containing Products, and further, has made false and/or misleading statements concerning the safety of ranitidine.

287. GSK possessed new information or new analyses of existing information that empowered it unilaterally to change the warnings and precautions section of its Ranitidine-Containing Products' label.

288. Despite this ability, GSK failed to warn of the risks of NDMA and its Ranitidine-Containing Products in the warnings and precautions section of its Ranitidine-Containing Products' label.

289. At all relevant times, the Ranitidine-Containing Products were defective at the time they left GSK's control. No extrinsic changes were made to alter the products GSK manufactured. The warnings Plaintiffs and their doctors observed were not changed from when they left GSK's control.

290. Plaintiffs were exposed to GSK's Ranitidine-Containing Products without knowledge of their dangerous characteristics.

291. At all relevant times, Plaintiffs used and/or were exposed to the use of GSK's Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

292. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of GSK to know about and disclose serious health risks associated with using GSK's products.

293. GSK knew or should have known that the minimal warnings disseminated with its Ranitidine-Containing Products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

294. The information that GSK did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid

using the drug. Instead, GSK disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to ranitidine; continued to aggressively promote the efficacy of Ranitidine-Containing Products, even after it knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting ranitidine.

295. Had GSK provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with its Ranitidine-Containing Products on the warnings and precautions section of its products' labels, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of GSK's concealment of the dangers posed by their Ranitidine-Containing Products, Plaintiffs were not alerted, and so could not avert their injuries.

296. GSK's conduct, as described above, was reckless. GSK risked the lives of consumers and users of its products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Products, and suppressed this knowledge from the general public. GSK made conscious decisions not to warn or inform the unsuspecting public. GSK's reckless conduct warrants an award of punitive damages.

297. GSK's lack of adequate warnings and instructions in the warnings and precautions section of its Ranitidine-Containing Products' labels were a substantial factor in causing Plaintiffs' injuries.

B. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR FAILURE TO WARN THROUGH PROPER EXPIRATION DATES

298. Ranitidine leads to NDMA exposure in the following ways: (1) the NDMA levels in ranitidine increase as the drug breaks down in the human digestive system and interacts with various enzymes in the human body; and (2) the ranitidine molecule internally degrades to form NDMA, and the NDMA levels in the drug substance and the drug product increase over time under normal storage conditions, but more so with exposure to heat or humidity.

299. NDMA is a potent carcinogen in humans. Higher exposures to NDMA over longer time periods lead to even higher risks of cancer.

300. To mitigate degradation of ranitidine into NDMA over time, and in the presence of heat or humidity, consumers should be warned to consume ranitidine shortly after manufacturing. No Ranitidine-Containing Product contained this warning.

301. In fact, Ranitidine-Containing Products had expiration dating periods of one or two years, allowing gradual accumulation of more and more unsafe levels of NDMA. A much shorter period of a matter of months would have ensured that ranitidine contained far lower levels of NDMA when consumed.

302. GSK knew or should have known about each of these risks in time to warn consumers. Simple, widely available and cost-effective tests reveal these risks.

303. In setting expiration and/or retest dates for its ranitidine-containing drugs, GSK was required to take into consideration the real-world conditions the drugs would be exposed to, including the conditions under which the drugs would be stored and shipped. See 21 C.F.R. §211.137.

304. In setting the expiration and/or retest dates for its ranitidine-containing drugs, GSK was also required to base those dates on stability testing, which in turn must account for storage conditions. 21 C.F.R. §211.166.

305. Storage conditions must account for conditions, including the storage container, heat, light, and humidity, among other things.

306. At all relevant times, GSK failed to adhere to its duties to set accurate expiration dates based upon stability testing that complied with its manufacturer's duty to account for these real-world conditions. These actions were under the ultimate control and supervision of GSK.

307. GSK designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold Ranitidine-Containing Products, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of ranitidine and NDMA.

308. At all relevant times, GSK failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of its products and to those who would foreseeably use or be harmed by GSK's Ranitidine-Containing Products.

309. Even though GSK knew or should have known that ranitidine posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to Ranitidine-Containing Products. The dangerous propensities of Ranitidine-Containing Products and the carcinogenic characteristics of NDMA, as described above, were known to GSK, or scientifically knowable to GSK through appropriate research and testing by known methods, at the time it distributed, supplied or sold the product, but were not known to end users and consumers, such as Plaintiffs.

310. GSK knew or should have known that Ranitidine-Containing Products created significant risks of serious bodily harm to consumers, as alleged herein, and GSK failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, and/or physicians of the risks of exposure to Ranitidine-Containing Products. GSK failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in Ranitidine-Containing Products, and further, have made false and/or misleading statements concerning the safety of ranitidine.

311. At all relevant times, the Ranitidine-Containing Products were defective at the time they left GSK's control. No extrinsic changes were made to alter the products GSK manufactured and sold. The expiration dates Plaintiffs and their doctors observed were not changed from when they left GSK's control.

312. Plaintiffs were exposed to GSK's Ranitidine-Containing Products without knowledge of their dangerous characteristics.

313. At all relevant times, Plaintiffs used and/or were exposed to the use of GSK's Ranitidine-Containing Products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

314. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Products prior to or at the time Plaintiffs consumed the drugs. Plaintiffs and their physicians relied upon the skill, superior knowledge, and judgment of GSK to know about and disclose serious health risks associated with using GSK's products.

315. GSK knew or should have known that the expiration dating periods disseminated with its Ranitidine-Containing Products were inadequate because they were long enough for dangerous levels of NDMA to build up in ranitidine.

316. This alleged failure to warn is not limited to the information contained on the section of the Ranitidine-Containing Products' label devoted to health warnings. GSK was able, in accord with federal law, to comply with relevant state law by providing a short expiration dating period that would accurately warn consumers not to consume ranitidine after significant portions of it had progressively deteriorated into NDMA. But GSK did not disclose these known risks through any medium.

317. Had GSK's provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Products, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of GSK's concealment of the dangers posed by their Ranitidine-Containing Products, Plaintiffs were not alerted, and so could not avert their injuries.

318. GSK's conduct, as described above, was reckless. GSK risked the lives of consumers and users of its products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Products, and suppressed this knowledge from the general public. GSK made conscious decisions not to redesign, warn or inform the unsuspecting public. GSK's reckless conduct warrants an award of punitive damages. GSK's lack of adequate warnings and instructions accompanying their Ranitidine-Containing Products were a substantial factor in causing Plaintiffs' injuries.

C. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS REGARDING NEGLIGENT PRODUCT CONTAINERS

319. As alleged above, GSK was required to conduct stability testing, which was required to take the container into account.

320. As previously alleged, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

321. GSK knew or should have known that ranitidine had an inherent risk of degrading into NDMA because it has both a nitroso (N) and dimethylamine (DMA), which are all the ingredients needed to form NDMA.

322. The Ranitidine-Containing Products Plaintiffs consumed had excessive levels of NDMA in part because they were subjected to high levels of humidity and were stored for a long period of time (often in humid locations such as bathrooms).

323. A substantial factor in NDMA formation was the container system manufacturers chose. Pill bottles with large numbers of units of ranitidine are likely to be stored for long periods by consumers after the seal is broken. This exposes the remaining units to humidity over time, which produces NDMA.

324. A different container would have reduced the amount of NDMA Plaintiffs consumed in several ways:

(a) Placing each unit of ranitidine in a blister pack or similar individually packaged container would ensure humidity control until the consumer used each unit.

(b) Reducing the number of units of ranitidine in each bottle to a low number would ensure the unused units were subject to humidity for only a shorter time period, since consumers would purchase new bottles more frequently.

325. GSK could have unilaterally changed the container system it sold. FDA guidance specifically allows changing the number of units in a non-sterile drug under its Changes Being Effected regulation. *See* FDA, Guidance for Industry, Changes to an Approved NDA or ANDA, Revision 1, at 21 (Apr. 2004), https://www.fda.gov/media/71846/download ("A change in the number of units (e.g., tablets, capsules) or labeled amount (e.g., grams, milliliters) of a nonsterile drug product in a unit-of-use container.").

326. FDA guidance also would treat changing to a unit-dose container such as a blister-pack to be a moderate change that could be implemented through the Changes Being Effected

regulation. *See id*. at 20–21 (only requiring pre-approval for sterile drug products, when moving from unit dose containers to multiple dose containers, rather than non-sterile drug products moving to unit dose containers).

327. A reasonably prudent manufacturer would have changed the containers for Ranitidine-Containing Products to protect the products from humidity and reduce the time between manufacture and consumption, both of which would reduce the amount of NDMA produced.

328. GSK's negligence was a substantial factor in causing Plaintiffs' injuries.

329. GSK's conduct, as described above, was reckless. GSK regularly risked the lives of consumers and users of its products, including Plaintiffs, with full knowledge of the dangers of its products. GSK has made conscious decisions not to change the containers for its Ranitidine-Containing Products.

D. ADDITIONAL ALLEGATIONS SPECIFIC TO PLAINTIFFS' COUNTS FOR NEGLIGENT STORAGE AND TRANSPORTATION

330. As alleged above, ranitidine degrades into NDMA more quickly at higher temperatures, at higher humidity levels, and under other poor storage or handling conditions.

331. GSK was well aware of the need to maintain sensitive pharmaceutical drugs under proper shipping and storage conditions, and that maintaining the highest safety techniques is best for the consumer. GSK is and was well aware of the importance of precise temperature control down to the degree as well as the importance of precise humidity control. More precise, colder transportation is, of course, more expensive than less precise, warmer transportation.

332. The temperature and humidity specifications placed on Ranitidine-Containing Products also affect the stability of Ranitidine-Containing Products.

333. NDMA forms due to chemical reactions in the human body, and degradation before consumption (principally heat, humidity, or time). Testing is performed before consumption and

the age of the ranitidine is documented, so neither time nor degradation in the body should produce substantial variation. The best inference must be that substantial variation in heat and humidity is causing differing amounts of NDMA to form.

334. GSK is aware that Ranitidine is highly sensitive to humidity and moisture. Ranitidine that is subjected to humidity and/or moisture, degrades quickly and forms excessive amount of NDMA.

335. GSK must account for these heat and humidity conditions and specifications in order to set proper shipping, storage and handling policies as well as accurate retest and expiration dates.

336. Testing of the quantity of NDMA in ranitidine performed to date has shown substantial variation among different batches. Some ranitidine has much more NDMA when tested, and some has less.

337. GSK admits that substantial variation exists in NDMA levels in its Ranitidine-Containing Products, and that levels increase over time but more so when subjected to heat and humidity.

338. Different Ranitidine-Containing Products listed slightly different storage and transportation requirements, but a common label requirement was "store at 20°C to 25°C (68°F to 77°F)" and "avoid excessive heat or humidity."

339. GSK transported finished drug product from its facilities to distributor warehouses, as well as storing finished drug products in its facilities.

340. GSK systematically caused Ranitidine-Containing Products to be exposed to excessive levels of heat and/or humidity during manufacture, storage, shipping and handling that

violated the instructions on the finished products' labels and caused ranitidine to degrade more quickly thereby increasing the levels of NDMA in the product.

341. Based upon the documents produced by the Brand Manufacturers and based upon further information and belief, GSK failed to ensure that its finished Ranitidine-Containing Products were stored and transported safely and were not exposed to excessive heat and humidity.

342. Based upon the documents produced by Brand Manufacturers and based upon further information and belief, GSK failed to ensure that API it stored, transported, or over which it could control storage or transportation, were not exposed to excessive heat and humidity.

343. GSK failed to implement rigorous policies to ensure substantial compliance with the heat and/or humidity requirements on product labels. This failure led to widespread noncompliance.

344. For example, GSK shipped Ranitidine-Containing Products through the mail. This method of transportation – whether through the United States Postal Service or large common carriers such as FedEx and UPS – does not guarantee controlled temperature or humidity. Because of GSK's choice to allow this method of transportation, Ranitidine-Containing Products shipped through the mail were systematically subject to excessive heat or humidity on days when the weather was hot or humid. In addition, GSK failed to properly monitor temperature and/or humidity levels during storage and transport.

345. Based upon the documents produced by Brand Manufacturers and based upon further information and belief, GSK failed to ensure that its Ranitidine-Containing Products were stored and transported safely and were not exposed to excessive heat and humidity and systematically exposed ranitidine to excessive levels of heat and humidity that violated the instructions on the products' labels.

346. GSK, directly or indirectly, transported, stored, handled, and/or sold Ranitidine-Containing Products that were used by Plaintiffs.

347. At all relevant times, GSK had a duty to exercise reasonable care in the storage and transportation of ranitidine API and Ranitidine-Containing Products to ensure the products were not unreasonably dangerous to consumers and users.

348. At all relevant times, GSK knew or should have known of the need for storing and transporting finished Ranitidine-Containing Products within the labeled temperature range and at low humidity, and for storing and transporting Ranitidine-Containing Products and ranitidine API at a reasonable, low temperature that would prevent degradation, and at low humidity.

349. GSK ignored this risk. It did not ensure ranitidine API and Ranitidine-Containing Products were stored at low humidity or within the temperature range on the label. Instead, ranitidine API and Ranitidine-Containing Products were subjected to excessive humidity and/or heat during transportation and shipping which caused the drug to degrade leading to the formation of excessive levels of NDMA.

350. Ignoring the risks of degradation and NDMA forming was unreasonable and reckless.

351. Plaintiffs did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Ranitidine-Containing Products.

352. GSK's negligence was a substantial factor in causing Plaintiffs' injuries.

VI. PLAINTIFFS' USE OF RANITIDINE-CONTAINING PRODUCTS AND ADDITIONAL MEDICAL MONITORING ALLEGATIONS

A. Plaintiffs Have a Significantly Increased Risk of Contracting a Subject Cancer Because the Zantac They Consumed Exposed them to NDMA at Levels Exceeding FDA's Acceptable Daily Intake.

353. As discussed in more detail above, Plaintiffs regularly ingested Ranitidine-Containing Products as a part of their treatment for gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

354. Plaintiffs used Zantac-branded Ranitidine-Containing Products designed, manufactured and/or sold by GSK. Those products, unbeknownst to Plaintiffs, transformed into dangerous levels of NDMA.

355. Based on prevailing scientific evidence, exposure to NDMA caused by consuming GSK's Ranitidine-Containing Products causes cancer in humans, including the serious and potentially fatal Subject Cancers.

356. Thus, as a direct and proximate result of consuming GSK's Ranitidine-Containing Products for years, Plaintiffs are at a significantly increased risk of contracting a Subject Cancer. Plaintiffs' lengthy duration of exposure to NDMA from Ranitidine-Containing Products warrants additional medical testing not routinely provided to the public at large.

357. It is undisputed that NDMA is a genotoxic and mutagenic carcinogen.

358. The FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 ng. An ADI is the "daily intake which, during up to an entire life of a human, appears to be without adverse effects or harm to the health of the consumer." 21 C.F.R. 556.3.

359. The FDA's ADI for NDMA can also be stated as 0.32 ppm for ranitidine.

360. According to the FDA, consumption of 96 ng of NDMA a day over a lifetime *increases* the risk of developing cancer by 0.001% (1:100,000). All consumers have a heightened

risk of contracting cancer.

361. Stated differently, according to the FDA, exposure to 2,452 micrograms of NDMA imposes a 1:100,000 chance of cancer.[163]

362. Exposure to more than 2,452 µg of NDMA, or 96 ng per day, is unacceptable and harmful by definition.

363. The risk of cancer increases as the level of NDMA exposure increases.

364. The FDA set its ADI for a reason—to protect individuals from harm, including cancer. It expects that pharmaceuticals that will expose a patient to more than 96 ng of NDMA a day will be recalled.

365. The Ranitidine-Containing Products regularly consumed by Plaintiffs, including those manufactured, marketed, and/or sold by GSK, contained NDMA in amounts many times greater than the 96 ng ADI, significantly increasing the risk that Plaintiffs will contract a Subject Cancer.

366. Emery's testing, discussed *supra,* confirmed that ranitidine is unstable and has a propensity to break down under higher temperatures, such as during storage and transport, forming NDMA.

367. The FDA's own testing found that ranitidine sold by Sanofi contained up to 360 ng of NDMA per 150 mg tablet—3 times the ADI[164] in just one dose—and Plaintiffs frequently took more than one dose a day.

368. [redacted]

[163] 96 ng x 365 days x 70 years = 2,452,800 ng, or 2,452 µg.

[164] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine. 1 microgram = 1000 nanograms.

[redacted][165] [redacted]

[redacted]

[redacted][166]

369. The Brand Manufacturer's figures do not include the increase in NDMA formation as a result of temperature and humidity imposed by storage and transportation conditions, as some of their samples were maintained in retention rooms in pristine conditions, or further formation of NDMA post-ingestion.

370. Following its evaluation of the Citizen Petition, the FDA initially stated that Ranitidine-Containing Products that contained NDMA in excess of the ADI were too dangerous to sell and should be recalled.[167]

371. Shortly thereafter, the FDA revised its directive. It concluded that because the level of NDMA continues to increase in ranitidine post-manufacture *it could not confirm that any Ranitidine Containing Product was safe from heightened levels of NDMA*, *full market withdrawal of ranitidine was warranted*.[168]

372. There are numerous studies, including epidemiological studies, that support the conclusion that NDMA and, specifically, NDMA in ranitidine, causes cancer in humans, including the Subject Cancers.

---

[165] GSKAN0000883508. Discovery is ongoing and it is anticipated that further information will be provided via expert reports and testimony.

[166] SANOFI_ZAN_MDL_0000038689.

[167] Thus while at times the FDA has referred to the levels of NDMA in the Ranitidine-Containing Products it tested as "low," such levels nonetheless exceeded the ADI, posed a significantly increased risk of harm, and necessitated recall and, ultimately, market withdrawal. Expert testimony will explain the significance of this exposure and the concomitant risk of cancer.

[168] FDA Letter, Woodcock, *supra* note 78.

373. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[169] Similarly, a more recent study revealed that individuals who consumed ranitidine have a 22% increase in bladder cancer as compared with non-users.[170]

374. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk, an effect that was even more pronounced in those with specific gene mutations.[171]

375. In another epidemiological study looking at various cancer risks and histamine H_2-receptor antagonists (or H_2 blockers), including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer. Of particular note, the study indicated that people under the age of 60 who took ranitidine were five times more likely to develop prostate cancer. In addition, there was more than a doubling of the risk of pancreatic cancer with ranitidine use.[172]

376. A study published in 2018 demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other H_2 blockers in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is particularly notable as the authors adjusted for variables.[173]

377. In 2018, a study found an increased risk in hepatocellular carcinoma associated

---

[169] Michaud et al., *supra* note 125.
[170] Cardwell, C. R., R. D. McDowell, C. M. Hughes, B. Hicks, and P. Murchie. *Exposure to Ranitidine and Risk of Bladder Cancer: A Nested Case-Control Study.* Am J Gastroenterol. 2021.
[171] Mathes, et al., *supra* note 127.
[172] Habel, et al., *supra* note 128.
[173] Tran, et al., *supra* note 129.

with use of H_2 blockers.[174] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H_2 blockers as a confounder. The study only considered use of H_2 blockers within one year of cancer diagnosis and still found an increased odds ratio associated with use of H_2 blockers and hepatocellular carcinoma, a type of liver cancer.

378. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H_2 blockers.[175] These cancers include breast, gastric, pancreatic, and stomach cancer. Additional research reports that ranitidine use was associated with a significant increase in the risk of bladder, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, and prostate cancer.[176]

379. Moreover, a 2015 meta-analysis demonstrated a 34% increased risk of gastric cancer when individuals consumed 190 ng to 270 ng of NDMA a day.[177] A 1998 study illustrates that with a daily intake of 270ng of NDMA, the risk of lung cancer is significantly increased.[178] And a 2011 study showed that there is a 46% increased risk of rectal cancer when 130 ng of NDMA are consumed a day.[179]

380. In addition to studies demonstrating that NDMA and, specifically, NDMA in ranitidine, directly causes cancer, research shows that exposure to NDMA (a) can exacerbate existing but dormant (*i.e.,* not malignant) tumor cells; (b) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (c) reduce the ability of the body to combat cancer as NDMA is immunosuppressive. Thus, in addition to NDMA being a direct cause of cancer itself,

[174] Shao, et al., *supra* note 130.
[175] Mathes et al., *supra* note 127; *see also supra,* note 131.
[176] Adamson et al., *supra* note 132.
[177] Song, et al., *supra,* note 133.
[178] DeStefani, et al., *supra,* note 134.
[179] Loh, et al., *supra* note 59.

NDMA can also be a contributing factor to a cancer injury caused by some other source.

381. Thus Plaintiffs, all of whom consumed Ranitidine-Containing Products for lengthy periods of time, were exposed to NDMA at levels many times greater than the FDA's ADI and are at a significantly increased risk of contracting the Subject Cancers. A reasonably prudent physician would recommend that Plaintiffs undergo diagnostic testing (medical monitoring) beyond that routinely recommended to the public at large.

382. As a direct and proximate result of GSK's unlawful conduct alleged herein, Plaintiffs have sustained a significantly increased risk of developing the Subject Cancers. Accordingly, they have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring that a reasonably prudent physician would deem necessary.

B. Plaintiffs and the Class Members Require Diagnostic Medical Testing that Differs from Routine Medical Care.

383. Physicians evaluate a person's exposure to toxic and carcinogenic substances, including NDMA, when determining what diagnostic medical testing and treatment is necessary.

384. A reasonably prudent physician would conclude that Plaintiffs' exposure to significant levels of NDMA over a lengthy period of time necessitates specialized testing (with resultant treatment) that is not generally given to the public at large as a part of routine medical care.

385. The available monitoring regime, discussed in greater detail below, is reasonably necessary and specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of exposure to NDMA. It is different from that normally recommended in the absence of exposure to this risk of harm (whether in kind and/or frequency) and is not generally available in a general practitioner setting.

386. The available medical monitoring regime will mitigate the development of and

health effects associated with the Subject Cancers, improving prognosis, outcome, and quality of life, and reducing medical costs.

387. Medical monitoring programs typically begin with screening to determine whether more invasive or costly tests are warranted. This screening may be conducted via questionnaire, in-person before a medical practitioner, or via a tele-health appointment.

388. When the medical practitioner reviewing the questionnaire or conducting the screening appointment determines additional testing for purposes of diagnosis is required, the testing for the Subject Cancers (bladder, colorectal/intestinal, esophageal, gastric, liver, lung, pancreatic, and prostate cancers) may include one or more of the tests described below, subject to the then-state-of-the-art standard of care or recommendations of the practitioners skilled in the diagnosis and treatment of the respective Subject Cancer.

389. Screening and testing in the medical monitoring program will likely occur for an extended period of time. This permits the medical practitioners to monitor changes in symptoms or follow anomalies that may appear in imaging or other tests over time, and accommodates latency periods associated with the Subject Cancers.

390. The following are examples only, and are subject to change, based on expert testimony and/or developing standards of care.

391. **Bladder Cancer.** Tests and procedures exist to detect bladder cancer early, but they are different and more extensive than routine medical care. Tests and procedures used to diagnose bladder cancer to be included in a medical monitoring program may include but not be limited to cystoscopy, in which a scope is used to examine the inside of a patient's bladder; urine cytology, which analyzes a sample of urine to check for cancer cells in conjunction with imaging tests, such as computerized tomography urogram or retrograde pyelogram, which allow the physician to

examine the structures of a patient's urinary tract.

392. The testing described above for bladder cancer is different than that normally recommended in the absence of Plaintiffs' exposure. It is not conducted or analyzed by a general practitioner or recommended to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including urologists, who specialize in diseases of the urinary tract and the male reproductive system, or urinary tract specialists.

393. While urinalysis may be conducted by a general practitioner to identify blood in the patient's urine, urinalysis is not a reliable method for diagnosing bladder cancer.

394. **Colorectal/intestinal cancer**. A procedure and test exist to detect colon cancer early, but they are different and more extensive than routine medical care.

395. The procedure and test used to diagnose colon cancer to be included in a medical monitoring program may include but not be limited to a colonoscopy, prescribed earlier and at a greater frequency than otherwise necessary. A colonoscopy uses a scope to examine the inside of the patient's colon. If any suspicious areas are found, the doctor can pass surgical tools through the tube to take tissue samples (biopsies) for analysis.

396. This testing is different than that normally recommended the absence of Plaintiffs' exposure. It is prescribed earlier and a greater frequency than appropriate for the public at large as a part of routine medical care. Further, it is conducted and analyzed by medical practitioners skilled in the respective areas, including gastroenterologists, which specialize in gastrointestinal diseases and have received specialized training in colonoscopy; pathologists, who specialize in evaluating cells, tissues and organs to diagnose disease; and cytologists, who specialize in the study of cells.

397. While blood tests may be used to test for a chemical sometimes produced by colon cancers (carcinoembryonic antigen, or CEA) as part of routine medical care, they cannot definitively diagnose colon cancer.

398. **Esophageal cancer**. Tests and procedures exist to detect esophageal cancer early, but they are different and more extensive than routine medical care. Tests and procedures used to diagnose esophageal cancer may include a barium swallow study, in which the patient swallows a liquid that includes barium and then undergoes X-rays; and an upper endoscopy, in which the physician passes a flexible tube equipped with a video lens (video endoscope) down the patient's throat and into their esophagus, looking for cancer or areas of irritation.

399. This testing is different than that normally recommended in the absence of Plaintiffs' exposure. For example, it is not conducted or analyzed by a general practitioner or recommended to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including radiologists or trained radiology technicians, who perform the barium swallow studies; and gastroenterologists, who specializes in the gastrointestinal tract and perform the endoscopy.

400. **Gastric cancer.** Tests and procedures exist to detect gastric cancer early, but they are different and more extensive than routine medical care. Tests and procedures used to diagnose gastric cancer to be included in a medical monitoring program may include but not be limited to a barium swallow study and an upper endoscopy.

401. A barium swallow study is performed by a radiologist or trained radiology technician, and an endoscopy is typically conducted by a gastroenterologist, who specializes in the gastrointestinal tract. These tests are different than what is normally recommended in the absence

of Plaintiffs' exposure and are not recommended to the public at large as a part of routine medical care.

402. **Liver cancer.** Tests and procedures exist to detect liver cancer early, but they are different and more extensive than routine medical care. Tests and procedures used to diagnose liver cancer to be included in a medical monitoring program may include but not be limited to imaging tests, including ultrasound, X-ray, CT or MRI, and which allow the physician to visualize a liver tumor or abnormality.

403. This testing is different than that normally recommended in the absence of Plaintiffs' exposure. For example, it is not conducted or analyzed by a general practitioner or recommended to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including but not limited to radiologists, who specialize in diagnosing and treating injuries and diseases using medical imaging procedures.

404. While blood tests may be used to determine if there is a liver function abnormality as part of routine medical care, they cannot definitively diagnose liver cancer.

405. **Lung cancer.** Tests and procedures exist to detect lung cancer early, but they are different and more extensive than routine medical care. Tests and procedures used to diagnose lung cancer to be included in a medical monitoring program may include but not be limited to imaging tests, including X-rays or CT scans that allow the physician to visualize a lung tumor or abnormality, and sputum cytology, which is the analysis of sputum (the mixture of saliva and mucus from the respiratory tract) under a microscope and which can reveal the presence of lung cancer cells.

406. This testing is different than that normally recommended the absence of Plaintiffs' exposure. For example, it is not conducted or analyzed by a general practitioner or available to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including but not limited to radiologists, who specialize in diagnosing and treating injuries and diseases using medical imaging procedures; pathologists, who specialize in interpreting laboratory tests and evaluating cells, tissues and organs to diagnose disease; and cytologists, who specialize in the study of cells.

407. **Pancreatic cancer.** Tests and procedures exist to detect pancreatic cancer early, but it is typically not diagnosed early because signs and symptoms of the disease do not appear until the disease is advanced, making monitoring particularly important. The tests and procedures to detect pancreatic cancer are different and more extensive than routine medical care.

408. Tests and procedures used to diagnose pancreatic cancer to be included in a medical monitoring program may include but not be limited to imaging tests such as ultrasound, X-ray, CT, MRI, or positron emission topography ("PET") scans, and which allow the physician to visualize a pancreatic tumor or abnormality, or endoscopic ultrasound, which uses an ultrasound device inside the abdomen to image the pancreas.

409. This testing is different than that normally recommended the absence of Plaintiffs' exposure. For example, it is not conducted or analyzed by a general practitioner or available to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including but not limited to radiologists, who specialize in diagnosing and treating injuries and diseases using medical imaging procedures; and gastroenterologists, which specialize in gastrointestinal diseases.

410. While blood tests may be used to test for certain proteins (tumor markers) shed by pancreatic cancer cells, the tests are not always reliable because some people with pancreatic cancer do not have elevated markers and thus the tests cannot definitively diagnose pancreatic cancer.

411. **Prostate cancer**. Tests and procedures exist to detect prostate cancer early, but they are not provided or recommended as part of routine medical care. Most medical organizations do not recommend screening for prostate cancer as part of routine medical care absent risk factors. Thus, the tests and procedures to detect prostate cancer are different and more extensive than routine medical care.

412. Tests and procedures used to diagnose prostate cancer to be included in a medical monitoring program may include but not be limited to the following.

413. Initial screening tests may detect abnormalities of the prostate but will not diagnose prostate cancer. Initial screening may include a digital rectal exam, in which a physician inserts a gloved, lubricated finger into the patient's rectum to examine their prostate, which is adjacent to the rectum, to identify any abnormalities in the texture, shape or size of the gland; and a Prostate-specific antigen (PSA) test, in which a blood sample is analyzed for excessive levels of PSA, a substance that's naturally produced by the prostate gland.

414. If prostate cancer screening detects an abnormality, tests and procedures used to diagnose prostate cancer include but may not be limited to measuring free PSA (to measure whether the percent of unbound PSA suggests the presence of cancer), a Transrectal ultrasound, in which a small probe is inserted into the patient's rectum to create a picture of the prostate gland, and an MRI.

415. This testing is different than that normally recommended the absence of Plaintiffs' exposure. For example, it is not conducted or analyzed by a general practitioner or available to the public at large as a part of routine medical care. Rather, it is conducted and analyzed by medical practitioners skilled in the respective areas, including but not limited to radiologists, who specialize in diagnosing and treating injuries and diseases using medical imaging procedures.

416. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical communities specializing in the diagnosis and treatment of the Subject Cancers.

417. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

418. Plaintiffs' physicians would not have prescribed and/or recommended Ranitidine-Containing Products to Plaintiffs, would have changed the way in which they treated Plaintiffs' relevant conditions, changed the way they warned Plaintiffs about the signs and symptoms of serious adverse effects of Ranitidine-Containing Products, and discussed with Plaintiffs the true risks of cancer, had GSK provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of Ranitidine-Containing Products.

419. Upon information and belief, Plaintiffs' physicians were unaware of the increased risk of multiple types of cancer associated with the use of Ranitidine-Containing Products due to ranitidine's transformation into NDMA and, if they had been informed, would have used, prescribed, and/or recommended alternative therapies to Plaintiffs.

420. Plaintiffs would not have used Ranitidine-Containing Products had Plaintiffs known of or been fully and adequately informed by GSK of the true increased risks and serious dangers of taking the drugs.

VII. TOLLING / FRAUDULENT CONCEALMENT

421. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

422. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

423. The nature of Plaintiffs' injuries, damages, or their causal relationship to GSK's conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

424. Plaintiffs bring this medical monitoring complaint within the applicable statute of limitations. Specifically, Plaintiffs bring this action within the prescribed time limits following Plaintiffs' awareness of their risk of injury and Plaintiffs' knowledge of the wrongful cause. Prior to such time, Plaintiffs did not know and had no reason to know of their injuries and/or the wrongful cause of those injuries.

425. The running of the statute of limitations is tolled due to equitable tolling. GSK is estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and omissions to Plaintiffs and defects associated with Ranitidine-Containing Products as they transform into NDMA. GSK affirmatively

withheld and/or misrepresented facts concerning the safety of ranitidine. As a result of GSK's misrepresentations and concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, of facts related to GSK's misrepresentations or omissions, that Plaintiffs had been exposed to the risks alleged herein, or that those risks were the direct and proximate result of the wrongful acts and/or omissions of GSK.

426. Given GSK's affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which GSK had exclusive control – and because Plaintiffs could not reasonably have known that GSK's Ranitidine-Containing Products were defective, GSK is estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

VIII. CLASS ALLEGATIONS

A. CLASS DEFINITIONS

427. Plaintiffs bring this action in their individual capacities and on behalf of their respective State Classes (described below), pursuant to Federal Rules of Civil Procedure 23(a), (b)(2)-(3), and/or (c)(4).

1. Prescription GSK Medical Monitoring Class

428. Plaintiffs identified in the table below bring claims against Defendant GSK on behalf of themselves and their respective State GSK Prescription Medical Monitoring Class, each of which is defined as "All individuals who used GSK's prescription Zantac while a resident of

[State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Michael Tomlinson	FL
Teresa Dowler	IN
Alberta Griffin	MD
Ronda Lockett	MO
Michael Galloway	OH
Felicia Ball	PA

2. OTC Medical Monitoring Classes

GSK

429. Plaintiffs identified in the table below bring claims against Defendant GSK on behalf of themselves and their respective State GSK OTC Medical Monitoring Class, each of which is defined as "All individuals who used GSK's OTC Zantac while a resident of [State] and have not been diagnosed with a Subject Cancer":

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Ricardo Moròn	FL
Ronda Lockett	MO
Jonathan Ferguson	NV

B. FED. R. CIV. P. 23 REQUIREMENTS

430. Each of the proposed State Classes meets the requirements of Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3) and/or 23(c)(4).

431. ***Numerosity.*** The members of each State Class are so numerous that joinder is impracticable. Zantac has for decades been one of the most popular medications for relief of heartburn, acid reflux, and similar conditions and, thus, it is reasonable to infer that each State Class includes thousands of members who are geographically dispersed.

432. ***Typicality.*** Plaintiffs' claims are typical of the claims of putative State Class members in that Plaintiffs' claims arise out of the same common course of conduct that gives rise to the claims of the other State Class members. Each Plaintiff, like each State Class member, took prescription and/or OTC Zantac, manufactured or sold by GSK, which are not safe for human consumption and, thus, Plaintiffs, like each State Class member, face an increased risk of developing any of the Subject Cancers. Plaintiffs, like each State Class member, were injured through GSK's misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the State Class members.

433. ***Adequacy.*** Plaintiffs will fairly and adequately protect the interests of the State Class members. Plaintiffs' interests and the interests of all other members of each respective State Class are identical and not antagonistic. Plaintiffs intend to vigorously prosecute this case and will fairly and adequately protect the State Class members' interests. Plaintiffs have retained counsel who are competent and experienced in litigating class actions, including litigation of this kind.

434. ***Commonality and Predominance.*** There are numerous questions of law and fact common to the State Classes, and these common questions predominate over any issues affecting only individual State Class members. Questions common to the State Classes include, but are not

limited to, the following:

(a) whether Zantac contains, or is likely to contain, or exposed State Class members to, unacceptable levels of NDMA;

(b) whether consumption of Zantac increases the risk of developing any of the Subject Cancers;

(c) whether GSK knew or should have known that Zantac contains, or is likely to contain, unacceptable levels of NDMA;

(d) whether GSK knew or should have known that consumption of Zantac increased the risk of developing any of the Subject Cancers;

(e) whether GSK acted to conceal the fact that Zantac exposes users to unacceptable quantities of NDMA;

(f) whether GSK acted to conceal the fact that consumption of Zantac increased the risk of developing cancer;

(g) whether GSK's warnings regarding the risks of cancer were adequate;

(h) whether GSK failed to warn consumers regarding the appropriate expiration dates for Zantac;

(i) whether GSK was negligent in labeling, marketing, advertising, promoting and/or manufacturing and/or selling Zantac;

(j) whether GSK was negligent in labeling, marketing, advertising, and/or promoting Zantac and its safety when used within the expiration dates;

(k) whether GSK was negligent in labeling, marketing, advertising, and/or promoting Zantac and its safety when used beyond the expiration dates;

(l) whether GSK was negligent in their storage and/or transportation of Zantac;

(m) whether GSK is liable for failing to warn of the risks associated with use of Zantac;

(n) whether Plaintiffs and State Class members are entitled to medical monitoring relief as a result of their increased risk of developing the Subject Cancers based on use of Zantac; and

(o) the type and format of medical monitoring relief, declaratory relief and/or injunctive relief that is appropriate.

435. ***Superiority.*** A class action is superior to other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiffs and the State Class are relatively small compared to the burden and expense required to individually litigate their claims against GSK, and thus, individual litigation to redress GSK's wrongful conduct would be impracticable. Individual litigation by each State Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

436. ***Injunctive and Declaratory Relief.*** Class certification is also appropriate under Rule 23(b)(2) because GSK acted and refused to act on grounds generally applicable to the State Class as a whole, such that final declaratory and/or injunctive relief is appropriate with respect to the State Class as a whole. Such declaratory and/or injunctive relief includes, but is not limited to, implementation and funding of a medical monitoring program for Plaintiffs and State Class members that is sufficient to monitor their health and ensure the early detection and diagnosis of diseases, specifically the Subject Cancers.

437. Plaintiffs reserve the right to seek certification of Rule 23(c)(4) of common questions related to GSK's knowledge, conduct, products, and duties.

IX. CAUSES OF ACTION

A. CAUSES OF ACTION AGAINST DEFENDANT GSK WITH RESPECT TO PRESCRIPTION ZANTAC

438. Plaintiffs identified in the table below bring claims against Defendant GSK with respect to prescription Zantac on behalf of themselves and their respective State GSK Prescription Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.C. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Golbenaz Bakhtiar	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Michael Tomlinson	FL
Teresa Dowler	IN
Alberta Griffin	MD
Ronda Lockett	MO
Michael Galloway	OH
Felicia Ball	PA

1. California

COUNT 1:
Negligence – Failure to Warn Through Warnings and Precautions – California

439. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and the Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-

426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

440. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

441. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 32-51, which are incorporated by reference.

442. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

443. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

444. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

445. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

446. As a direct and proximate result of Defendant's failure to provide adequate

warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

447. The latent injuries from which Plaintiff and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

448. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

449. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

450. By monitoring and testing Plaintiffs, the risk that Plaintiff and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

451. Plaintiff and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiff and the California GSK Prescription Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

452. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

453. Plaintiff and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiff and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 2:
Negligence – Failure to Warn Through Proper Expiration Dates – California

454. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

455. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf

of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

456. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in paragraphs 32-51, which are incorporated by reference.

457. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

458. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

459. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiff that Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

460. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

461. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

462. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

463. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

464. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

465. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

466. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

467. Accordingly, Defendant should be required to establish a medical monitoring

program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

468. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 3:
Negligent Product Containers – California

469. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

470. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

471. The allegations in this Count apply to GSK during the time periods in which it was manufacturing Ranitidine-Containing Products. The relevant time periods are alleged in

paragraphs 32-51, which are incorporated by reference.

472. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

473. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

474. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

475. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

476. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

477. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

478. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

479. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

480. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiff and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

481. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

482. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiff and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 4:
Negligent Storage and Transportation – California

483. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

484. This cause of action is brought by Golbenaz Bakhtiar, individually and on behalf of the California GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

485. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

486. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

487. Under California law, a pharmaceutical manufacturer, including Defendant, has a duty to exercise reasonable care in transporting and storing products.

488. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

489. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the California GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

490. The latent injuries from which Plaintiffs and the California GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

491. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

492. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

493. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

494. Plaintiffs and the California GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

495. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

496. Plaintiffs and the California GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the California GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 5:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Colorado

497. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-

173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

498. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

499. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

500. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

501. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

502. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

503. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

504. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

505. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

506. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

507. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

508. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

509. By monitoring and testing Plaintiffs, the risk Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

510. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

511. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

512. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a Court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 6:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Colorado

513. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

514. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

515. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

516. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

517. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

518. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

519. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

520. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

521. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

522. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

523. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

524. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

525. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

526. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

527. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

528. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 7:
Medical Monitoring – Negligent Product Containers – Colorado

529. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

530. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

531. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

532. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

533. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

534. Under Colorado law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

535. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

536. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

537. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

538. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

539. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

540. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

541. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

542. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

543. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 8:
Medical Monitoring – Negligent Storage and Transportation – Colorado

544. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

545. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

546. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

547. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

548. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

549. Under Colorado law, Defendant has a duty to exercise reasonable care in transporting and storing products.

550. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

551. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

552. The latent injuries from which Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment)

that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

553. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

554. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

555. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

556. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

557. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing

Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

558. Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 9:
Medical Monitoring – Negligence – Failure to Warn Through Warnings and Precautions – Florida

559. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

560. This cause of action is brought by Michael Galloway, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

561. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

562. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

563. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

564. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

565. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

566. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

567. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the

Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

568. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

569. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

570. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

571. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

572. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

573. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

574. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 10:
Medical Monitoring – Negligence – Failure to Warn Through Proper Expiration Dates – Florida

575. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

576. This cause of action is brought by Michael Galloway, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

577. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

578. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

579. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

580. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

581. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

582. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

583. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Florida GSK Prescription

Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

584. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

585. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

586. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

587. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

588. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

589. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

590. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 11:
Medical Monitoring – Negligent Product Containers – Florida

591. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

592. This cause of action is brought by Michael Galloway and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

593. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

594. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

595. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

596. Under Florida law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

597. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

598. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

599. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

600. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

601. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

602. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

603. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

604. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

605. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

606. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 12:
Medical Monitoring – Negligent Storage and Transportation – Florida

607. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

608. This cause of action is brought by Michael Galloway, and Michael Tomlinson, individually and on behalf of the Florida GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

609. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

610. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

611. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

612. Under Florida law, Defendant has a duty to exercise reasonable care in transporting and storing products.

613. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

614. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and Florida GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

615. The latent injuries from which Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

616. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

617. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

618. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

619. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

620. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Florida GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

621. Plaintiffs and the Florida GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Indiana

COUNT 13:
Negligence – Failure to Warn Through Warnings and Precautions – Indiana

622. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

623. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

624. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

625. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

626. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

627. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were unreasonably inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

628. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

629. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

630. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

631. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

632. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

633. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

634. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

635. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

636. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 14:
Negligence – Failure To Warn Through Proper Expiration Dates – Indiana

637. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein

638. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

639. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

640. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

641. Under Indiana law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate instructions for safe use and a warning as to dangers inherent in improper use.

642. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

643. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

644. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

645. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

646. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

647. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

648. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

649. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

650. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

651. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 15:
Negligent Product Containers – Indiana

652. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

653. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

654. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

655. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

656. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

657. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

658. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

659. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

660. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

661. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

662. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

663. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

664. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

665. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 16:
Negligent Storage and Transportation – Indiana

666. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

667. This cause of action is brought by Teresa Dowler, individually and on behalf of the Indiana GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

668. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

669. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

670. Under Indiana law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

671. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

672. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

673. The latent injuries from which Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

674. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

675. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

676. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

677. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

678. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Indiana GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

679. Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Indiana GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Maryland

COUNT 17:
Negligence – Failure to Warn Through Warnings and Precautions – Maryland

680. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

681. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

682. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

683. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

684. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

685. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

686. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

687. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

688. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

689. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

690. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

691. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

692. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

693. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

694. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 18:
Negligence – Failure To Warn Through Proper Expiration Dates – Maryland

695. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

696. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

697. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

698. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

699. Under Maryland law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of a danger it knew or should have had known about.

700. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

701. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

702. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

703. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

704. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

705. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

706. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

707. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

708. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

709. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 19:
Negligent Product Containers – Maryland

710. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

711. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

712. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

713. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

714. Under Maryland law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

715. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

716. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

717. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

718. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

719. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

720. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

721. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will

facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

722. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

723. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 20:
Negligent Storage and Transportation – Maryland

724. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Non-Party Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing GSK's and Non-Party Manufacturers' knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

725. This cause of action is brought by Alberta Griffin, individually and on behalf of the Maryland GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

726. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

727. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

728. Under Maryland law, Defendant had a duty to exercise reasonable care in transporting and storing products.

729. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

730. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, transported, and, therefore, Plaintiffs and Maryland GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

731. The latent injuries from which Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

732. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

733. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

734. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

735. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

736. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Maryland GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

737. Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Maryland GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

6. Missouri

COUNT 21:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

738. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

739. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

740. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

741. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

742. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

743. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

744. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

745. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

746. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

747. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

748. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

749. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

750. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

751. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

752. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 22:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

753. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

754. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

755. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

756. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

757. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

758. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

759. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

760. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

761. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

762. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers.

This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

763. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

764. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

765. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

766. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

767. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without

a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 23: Negligent Product Containers – Missouri

768. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

769. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

770. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

771. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

772. Under Missouri law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

773. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

774. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and,

therefore, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

775. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

776. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

777. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

778. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

779. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class

members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

780. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

781. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 24: Negligent Storage and Transportation – Missouri

782. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

783. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

784. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

785. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

786. Under Missouri law, Defendant has a duty to exercise reasonable care in transporting and storing products.

787. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

788. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

789. The latent injuries from which Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

790. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

791. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

792. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

793. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

794. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Missouri GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

795. Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

7. Ohio

COUNT 25:
Strict Liability – Failure to Warn Through Warnings and Precautions – Ohio

796. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

797. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

798. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

799. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

800. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

801. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on each Ranitidine-Containing Product were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

802. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

803. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

804. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

805. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

806. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

807. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

808. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

809. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

810. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 26:
Strict Liability – Failure To Warn Through Proper Expiration Dates – Ohio

811. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

812. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

813. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

814. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

815. Under Ohio law, a manufacturer, like Defendant, has the duty to provide an adequate warning of the risks associated with its product that it knows or should have known about, and a duty to provide adequate post-marketing warnings or instructions.

816. Defendant breached this duty for the Ranitidine-Containing it manufactured. The warnings included on each Ranitidine-Containing Product were inadequate because The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

817. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

818. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

819. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of

ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

820. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

821. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

822. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

823. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

824. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

825. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 27:
Negligent Product Containers – Ohio

826. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

827. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

828. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

829. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

830. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

831. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

832. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold. These high levels of NDMA caused Plaintiffs' injuries.

833. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

834. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

835. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

836. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

837. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

838. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

839. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

840. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 28:
Negligent Storage and Transportation – Ohio

841. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

842. This cause of action is brought by Michael Galloway, individually and on behalf of the Ohio GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

843. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

844. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

845. Under Ohio law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in transporting and storing products.

846. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

847. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

848. The latent injuries from which Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

849. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

850. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

851. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

852. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

853. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Ohio GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

854. Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Ohio GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

8. Pennsylvania

COUNT 29:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Pennsylvania

855. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173

(describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

856. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

857. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

858. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

859. Under Pennsylvania law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning.

860. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

861. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs

would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

862. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

863. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

864. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

865. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

866. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

867. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

868. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

869. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 30:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Pennsylvania

870. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer),

183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

871. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

872. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

873. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

874. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

875. Under Pennsylvania law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning.

876. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

877. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

878. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

879. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

880. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

881. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

882. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

883. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program

which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

884. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

885. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 31:
Medical Monitoring – Negligent Product Containers – Pennsylvania

886. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

887. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

888. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

889. Plaintiffs incorporate herein by reference Paragraphs 319-329 (Additional Count-Specific Allegations) as to GSK.

890. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

891. Under Pennsylvania law, a pharmaceutical manufacturer, like Defendant, has a duty to exercise reasonable care in choosing and making the containers for its products.

892. Defendant breached this duty by failing to utilize containers that would minimize the NDMA produced in its Ranitidine-Containing Products.

893. As a direct and proximate result of this failure, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant sold, and, therefore, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

894. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers

because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

895. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

896. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

897. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

898. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

899. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b)

notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

900. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 32:
Medical Monitoring – Negligent Storage and Transportation – Pennsylvania

901. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein. This cause of action is brought by Felicia Ball, individually and on behalf of the Pennsylvania GSK Prescription Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

902. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

903. Plaintiffs incorporate herein by reference Paragraphs 330-352 (Additional Count-Specific Allegations) as to GSK.

904. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

905. Under Pennsylvania law, Defendant has a duty to exercise reasonable care in transporting and storing products.

906. Defendant breached this duty by failing to implement or enforce policies to ensure Ranitidine-Containing Products and ranitidine API remained free from excessive heat and humidity.

907. As a direct and proximate result of these systematic failures, excessive levels of NDMA built up in the Ranitidine-Containing Products Defendant manufactured, stored, and transported, and, therefore, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

908. The latent injuries from which Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

909. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

910. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

911. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

912. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members as frequently and appropriately as necessary.

913. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Pennsylvania GSK Prescription Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

914. Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the

Court, Plaintiffs and the Pennsylvania GSK Prescription Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

B. CAUSES OF ACTION AGAINST DEFENDANT GSK WITH RESPECT TO OTC ZANTAC

915. Plaintiffs identified in the table below bring claims against Defendant GSK with respect to OTC Zantac on behalf of themselves and their respective State GSK OTC Medical Monitoring Class under the laws of their respective states of usage. Each Plaintiff incorporates by reference the allegations specific to them from Section III.C. and the allegations set forth in Section VI, *supra,* into their respective claims below.

Plaintiff Name	**State of Usage**
Richard Obrien	CA
Jeffrey Pisano	CO
Michael Galloway	FL
Ricardo Moròn	FL
Ronda Lockett	MO
Jonathan Ferguson	NV

1. California

COUNT 33:
Negligence – Failure to Warn Through Warnings and Precautions – California

916. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

917. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

918. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

919. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

920. Under California law, manufacturers, like Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

921. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk

of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

922. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

923. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

924. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

925. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

926. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

927. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

928. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

929. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

930. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 34:
Negligence – Failure to Warn Through Proper Expiration Dates – California

931. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

932. This cause of action is brought by Richard Obrien, individually and on behalf of the California GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

933. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

934. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

935. Under California law, manufacturers, including Defendant, have a duty of reasonable care to warn of particular risks that are known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

936. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

937. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

938. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and California GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

939. The latent injuries from which Plaintiffs and the California GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

940. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

941. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

942. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the California GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

943. Plaintiffs and the California GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the California GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the California GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

944. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all California GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

945. Plaintiffs and the California GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court,

Plaintiffs and the California GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

2. Colorado

COUNT 35:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Colorado

946. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

947. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

948. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

949. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

950. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

951. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

952. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

953. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

954. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

955. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

956. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

957. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

958. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

959. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

960. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

961. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 36:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Colorado

962. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

963. This cause of action is brought by Jeffrey Pisano, individually and on behalf of the Colorado GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

964. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

965. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

966. Plaintiff's exposure to Ranitidine-Containing Products has significantly increased their risk of developing various types of serious and potentially fatal Subject Cancers.

967. Under Colorado law, a manufacturer, like Defendant, has a duty of reasonable care to provide adequate warnings or instructions for use that adequately inform the user of any specific risk of harm that may be involved in any intended or reasonably expected use.

968. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

969. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

970. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

971. The latent injuries from which Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

972. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

973. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

974. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

975. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

976. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Colorado GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

977. Plaintiffs and the Colorado GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Colorado GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

3. Florida

COUNT 37:
Medical Monitoring – Negligent Failure to Warn Through Warnings and Precautions – Florida

978. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

979. This cause of action is brought by Michael Galloway and Ricardo Moron, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

980. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

981. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

982. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

983. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

984. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

985. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

986. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and Florida GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

987. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

988. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

989. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

990. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

991. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

992. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

993. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 38:
Medical Monitoring – Negligent Failure to Warn Through Proper Expiration Dates – Florida

994. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

995. This cause of action is brought by Michael Galloway and Ricardo Moron, individually and on behalf of the Florida GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

996. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

997. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

998. Plaintiffs' exposure to Ranitidine-Containing Products has significantly increased their risk of developing serious and potentially fatal Subject Cancers.

999. Under Florida law, a manufacturer, like Defendant, has the duty of reasonable care to provide an adequate warning of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.

1000. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1001. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1002. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Florida GSK OTC

Medical Monitoring Class members have sustained a significantly increased risk of developing the Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1003. The latent injuries from which Plaintiffs and the Florida GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1004. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1005. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1006. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1007. Plaintiffs and the Florida GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical

monitoring and diagnosis of Plaintiffs and the Florida GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1008. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Florida GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1009. Plaintiffs and the Florida GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Florida GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

4. Missouri

COUNT 39:
Negligence – Failure to Warn Through Warnings and Precautions – Missouri

1010. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1011. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1012. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

1013. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

1014. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1015. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1016. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1017. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1018. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1019. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1020. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1021. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1022. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for

the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1023. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1024. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 40:
Negligence – Failure to Warn Through Proper Expiration Dates – Missouri

1025. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1026. This cause of action is brought by Ronda Lockett, individually and on behalf of the Missouri GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1027. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

1028. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

1029. Under Missouri law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1030. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1031. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1032. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1033. The latent injuries from which Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1034. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1035. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1036. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1037. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1038. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Missouri GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1039. Plaintiffs and the Missouri GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Missouri GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

5. Nevada

COUNT 41:
Negligence – Failure to Warn Through Warnings and Precautions – Nevada

1040. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1041. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1042. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

1043. Plaintiffs incorporate herein by reference paragraphs 259-297 (Additional Count-Specific Allegations) as to GSK.

1044. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1045. Defendant breached this duty for its Ranitidine-Containing Products. The warnings included on Ranitidine-Containing Products were inadequate because they did not warn of the risk of cancer when taken over long periods, when stored under humid conditions, when stored under hot conditions, when consumed with a high-nitrite diet, and when consumed long after manufacture.

1046. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1047. As a direct and proximate result of Defendant's failure to provide adequate warnings of the risk of Ranitidine-Containing Products, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing

serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1048. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1049. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1050. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1051. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1052. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical

monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1053. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1054. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

COUNT 42:
Negligence – Failure to Warn Through Proper Expiration Dates – Nevada

1055. Plaintiffs incorporate by reference each allegation set forth in paragraphs 5-12 (describing GSK and Brand Manufacturers), 53-117 (describing the recall of ranitidine), 118-173 (describing the formation of ranitidine), 174-182 (describing evidence linking ranitidine to cancer), 183-187 (describing Defendant's knowledge), 197-208 (describing good manufacturing practices), 209-232 (describing GSK's failure to warn), 262-288 (describing Brand OTC Manufacturers' failure to warn), and 353-426 (describing Plaintiffs' use of ranitidine and injury), as if fully stated herein.

1056. This cause of action is brought by Jonathan Ferguson, individually and on behalf of the Nevada GSK OTC Medical Monitoring Class (for the purposes of this Count, "Plaintiffs"), against GSK (for the purposes of this Count, "Defendant").

1057. The allegations in this Count apply to GSK during the time period in which it was manufacturing Ranitidine-Containing Products. The relevant time period is alleged in paragraphs 32-51, which are incorporated by reference.

1058. Plaintiffs incorporate herein by reference Paragraphs 298-318 (Additional Count-Specific Allegations) as to GSK.

1059. Under Nevada law, a manufacturer, like Defendant, has a duty of reasonable care to provide an adequate warning of the risks of its products.

1060. Defendant breached this duty for its Ranitidine-Containing Products. The expiration date improperly instructed Plaintiffs that its Ranitidine-Containing Products were safe when consumed long after manufacture, when in fact the products degraded into NDMA over time.

1061. Plaintiffs or their doctors would have read and heeded these warnings had they been included with the Ranitidine-Containing Products. Had such warnings been provided, Plaintiffs would have been made aware of the risks of developing the Subject Cancers associated with the use of the Ranitidine-Containing Products.

1062. As a direct and proximate result of Defendant's failure to provide an adequate warning of the risks of Ranitidine-Containing Products, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members have sustained a significantly increased risk of developing serious and potentially fatal Subject Cancers and have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

1063. The latent injuries from which Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members suffer require specialized testing (with resultant treatment) that is not generally given to the public at large. The available monitoring regime is specific for individuals exposed to products known to significantly increase the risk of the Subject Cancers because of ingesting Ranitidine-Containing Products and is different from that normally recommended in the absence of exposure to this risk of harm.

1064. The medical monitoring regime should include, but is not limited to, baseline tests and diagnostic examination that will assist in early detection and diagnosing the Subject Cancers. This diagnostic program will facilitate treatment and interventions that will mitigate the development of, and health effects associated with, the Subject Cancers.

1065. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the Subject Cancers.

1066. By monitoring and testing Plaintiffs, the risk that Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will suffer long-term injuries, disease, and losses without adequate treatment will be significantly reduced.

1067. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members seek creation of a Court-supervised, Defendant-funded medical monitoring program which will facilitate the diagnoses of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members for the Subject Cancers. The medical monitoring should include a trust fund to pay for the medical monitoring and diagnosis of Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members as frequently and appropriately as necessary.

1068. Accordingly, Defendant should be required to establish a medical monitoring program that includes, among other things: (a) establishing a trust fund, in an amount to be determined, to pay for the medical monitoring of everyone who has taken Ranitidine-Containing Products for the purpose of diagnosis, as frequently and appropriately as necessary; and (b) notifying all Nevada GSK OTC Medical Monitoring Class members in writing that they may require frequent medical monitoring for the purpose of diagnosis.

1069. Plaintiffs and the Nevada GSK OTC Medical Monitoring Class have an inadequate remedy at law in that monetary damages alone cannot compensate them for the risk of long-term physical and economic losses due to ingesting Ranitidine-Containing Products. Without a court-approved medical monitoring program as described herein, or established by the Court, Plaintiffs and the Nevada GSK OTC Medical Monitoring Class members will continue to face an unreasonable risk of injury and disability and remain undiagnosed.

X. PRAYER FOR RELIEF

Plaintiffs, on behalf of themselves and the proposed State Classes, respectfully request that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4), direct that reasonable notice of this action be given to the State Classes, appoint Plaintiffs as named representatives of their respective State Classes, and appoint Plaintiffs' counsel as Class Counsel;

B. Enter judgment against GSK and in favor of Plaintiffs and the State Classes;

C. Grant equitable relief in the form of a medical monitoring program to be funded by GSK;

D. Award Plaintiffs and the State Classes their costs of suit, including reasonable attorneys' fees, as provided by law;

E. Award any other relief that is deemed just and proper.

XI. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the State Classes, demand a trial by jury on all issues to triable.

DATED: January 24, 2022

Respectfully submitted,

/s/ Lynn A. Ellenberger
Lynn A. Ellenberger
FEGAN SCOTT LLC
500 Grant St., Suite 2900
Pittsburgh, PA 15219
Tel: (412) 346-4104
lynn@feganscott.com

FILED ON BEHALF OF:

Plaintiffs' Lead Counsel

Tracy A. Finken
Email: tfinken@anapolweiss.com
ANAPOL WEISS
One Logan Square
130 North 18th Street, Suite 1600
Philadelphia, PA 19103
Tel: (215) 735-1130

Robert C. Gilbert, FBN 561861
Email: gilbert@kolawyers.com
KOPELOWITZ OSTROW FERGUSON
WEISELBERG GILBERT
2800 Ponce de Leon Boulevard, Suite 1100
Coral Gables, FL 33134
Tel: (305) 384-7269

Michael L. McGlamry
Email: efile@pmkm.com
POPE McGLAMRY, P.C.
3391 Peachtree Road NE, Suite 300
Atlanta, GA 30326
Tel: (404) 523-7706

Adam Pulaski
Email: adam@pulaskilawfirm.com
PULASKI KHERKHER, PLLC
2925 Richmond Avenue, Suite 1725
Houston, TX 77098
Tel: (713) 664-4555

Plaintiffs' Co-Lead Counsel

Rosemarie Riddell Bogdan
Email: Rosemarie.bogdan@1800law1010.com

Mark J. Dearman, FBN 0982407
Email: mdearman@rgrdlaw.com

MARTIN, HARDING & MAZZOTTI
1222 Troy-Schenectady Road
PO Box 15141
Albany, NY 12212
Tel.: (518) 862-1200

ROBBINS GELLER RUDMAN & DOWD
120 East Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Tel.: (561) 750-3000

Elizabeth A. Fegan
Email: beth@feganscott.com
FEGAN SCOTT, LLC
150 S. Wacker Dr., 24th Floor
Chicago, IL 60606
Tel.: (312) 741-1019

Marlene J. Goldenberg
Email: mjgoldenberg@goldenberglaw.com
GOLDENBERG LAW, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
Tel.: (612) 333-4662

Ashley Keller
Email: ack@kellerlenkner.com
KELLER | LENKNER
150 N. Riverside Plaza, Suite 4270
Chicago, IL 60606
Tel.: (312) 741-5222

Frederick Longer
Email: flonger@lfsblaw.com
LEVIN SEDRAN & BERMAN
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel.: (215) 592-1500

Roopal P. Luhana
Email: luhana@chaffinluhana.com
CHAFFIN LUHANA LLP
600 Third Avenue, 12th Floor
New York, NY 10016
Tel.: (888) 480-1123

Francisco R. Maderal, FBN 0041481
Email: frank@colson.com
COLSON HICKS EIDSON
255 Alhambra Circle, Penthouse
Coral Gables, FL 33134
Tel.: (305) 476-7400

Ricardo M. Martinez-Cid, FBN 383988
Email: RMartinez-Cid@Podhurst.com
PODHURST ORSECK, P.A.
SunTrust International Center
One S.E. 3rd Avenue, Suite 2300
Miami, FL 33130
Tel.: (305) 358-2800

Lauren S. Miller
Email: lmiller@corywatson.com
CORY WATSON, P.C.
2131 Magnolia Ave S
Birmingham, AL 35205
Tel.: (205) 328-2200

Melanie H. Muhlstock
Email: mmuhlstock@yourlawyer.com
PARKER WAICHMAN LLP
6 Harbor Park DrivePort
Washington, NY 11050
Tel.: (516) 466-6500

Daniel A. Nigh, FBN 30905
Email: dnigh@levinlaw.com
LEVIN PAPANTONIO THOMAS
MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street, Suite 600
Pensacola, FL 32502
Tel.: (888) 435-7001

Carmen S. Scott
Email: cscott@motleyrice.com
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Tel.: (843) 216-9160

Mikal C. Watts
Email: mcwatts@wattsguerra.com
WATTS GUERRA LLP
4 Dominion Drive
Building 3, Suite 100
San Antonio, TX 78257
Tel.: (800) 294-0055

Sarah N. Westcot, FBN 1018272
Email: swestcot@bursor.com
BURSOR & FISHER, P.A.
2665 S. Bayshore Drive, Suite 220
Miami, FL 33133
Tel.: (305) 330-5512

Conlee S. Whiteley
Email: c.whiteley@kanner-law.com
KANNER & WHITELEY, L.L.C.
701 Camp Street
New Orleans, LA 70130
Tel.: (504) 524-5777

Frank Woodson
Email: Frank.Woodson@BeasleyAllen.com
BEASLEY ALLEN LAW FIRM
218 Commerce Street
Montgomery, AL 36104
Tel.: (334) 269-2343

R. Brent Wisner
Email: rbwisner@baumhedlundlaw.com
BAUM HEDLUND ARISTEI &
GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
Tel.: (310) 207-3233

Plaintiffs' Steering Committee
Plaintiffs' Law and Briefing Committee Co-Chairs
Plaintiffs' Liaison Counsel

Paige Boldt
Email: pboldt@wattsguerra.com
WATTS GUERRA LLP
5726 W. Hausman Rd., Ste. 119
San Antonio, TX 78249
Tel: (210) 447-0500

Je Yon Jung
Email: JJung@maylightfootlaw.com
MAY LIGHTFOOT, PLLC
3200 Martin Luther King Jr. Avenue S.E.
3rd Floor
Washington, DC 20032
Tel: (202) 918-1824

Adam W. Krause
Email: adam@krauseandkinsman.com
KRAUSE AND KINSMAN, LLC
4717 Grand Avenue, Suite 250
Kansas City, MO 64112
Tel: (816) 760-2700

Nicola Larmond-Harvey, FBN 0105312
Email: nicola@saunderslawyers.com
SAUNDERS & WALKER, P.A.
3491 Gandy Boulevard North, Suite 200
Pinellas Park, FL 33781
Tel: (727) 579-4500

Bradford B. Lear
Email: Lear@learwerts.com
LEAR WERTS LLP
103 Ripley Street
Columbia, MO 65203
Tel: (573) 875-1992

Plaintiffs' Leadership Development Committee